Stakeholder Workshop on EFSA's Genotoxicity Guidance Revision 3-4 November 2025, Brussels



REVISION OF EFSA'S GENOTOXICITY GUIDANCE FRAMEWORK & STAKEHOLDER WORKSHOP

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REVISION OF EFSA'S GENOTOXICITY GUIDANCE FRAMEWORK



INTRODUCTION

- The EFSA Scientific Committee has initiated, as a self-task, the revision of the Scientific Opinion on genotoxicity testing strategies (EFSA, 2011) and the additional guidance documents (i.e., genotoxicity guidance framework).
- <u>General goal:</u> Merging of all 5 EFSA's genotoxicity guidance documents into a single guidance with updated information and approaches by considering the state-of-the-art in genotoxicity assessment.
- Engagement activities with relevant stakeholders:
- Public Consultation of scoping paper with the draft Terms of Reference (15/12/2024 31/1/2025)
 - Stakeholder Workshop (3 & 4/11/2025 in Brussels)
 - Target and Public Consultations of the draft guidance
 - Following publication, webinar and training sessions for the new guidance



EFSA'S GENOTOXICITY GUIDANCE FRAMEWORK

Currently, EFSA's genotoxicity guidance framework consists of <u>5 documents</u>:

- Scientific opinion on **genotoxicity testing strategies** applicable to food and feed safety assessment (EFSA, 2011).
- Clarification of some aspects related to genotoxicity assessment (EFSA, 2017).
- Genotoxicity assessment of chemical mixtures (EFSA, 2019).
- Guidance on aneugenicity assessment (EFSA, 2021).
- Harmonised approach for reporting **reliability and relevance** of genotoxicity studies (EFSA, 2023).



OVERVIEW OF THE GUIDANCE REVISION & UPDATE

1

- Genotoxicity testing strategy
- Bone marrow and target tissue exposure
- Aneugenicity assessment
- Genotoxicity assessment of mixtures

1: Main areas to be considered in guidance revision

2

- Quantitative genotoxicity assessment
- Clarification on the role of NAMs and QSAR models in the testing strategy in accordance with 3R principles
- Genotoxicity assessment of specific materials or substances (nanomaterials, proteins, etc.)

❖ 2: New aspects to be included in the guidance



NEW GENOTOXICITY GUIDANCE KEY FEATURES

- The **revised and updated guidance** will be used by <u>both applicants and risk</u> <u>assessors</u> (e.g. EFSA's Panels), as is the case with the current guidance documents.
- **Understandable and practical.** To develop a concise and usable core guidance document. Essential background information will be included in Annexes.
- The updated testing strategy will consider current **state-of-the-art** in genotoxicity assessment and novel methodologies.
- The aim is also to address issues or ambiguities identified in the application of the current genotoxicity guidance framework.
- Be in alignment with other international genotoxicity guidance documents to the extent possible, particularly with **EU sister agencies**.



WORKPLAN

Work started in the end of Q1 2025 for an estimated 2-year period (Expected publication: Q2 2027)

Preparatory Phase

- Literature review of the state-of-the-art in genotoxicity assessment
- Review approaches from other international organisations (OECD, WHO, etc.)
- Start of the Genotoxicity WG Guidance meetings
- Establishing active collaboration with EU agencies and bodies (e.g. ECHA, EMA, SCCS, JRC) and engagement with other international organisations

Design Phase

- Revision of the guidance and drafting of new text
- Workshop with relevant stakeholders to gather feedback on the application of existing EFSA genotoxicity guidance documents (Q4 2025)
- Target consultations with EFSA's Units/Panels and sister agencies (Q4 2026)
- Public Consultation (Q1 2027)

Adoption Phase

- Revision of the draft guidance based on comments received during Target and Public Consultations
- Adoption of the new guidance by the Scientific Committee of EFSA and publication
- Info session/webinar with relevant stakeholders

Dissemination Phase

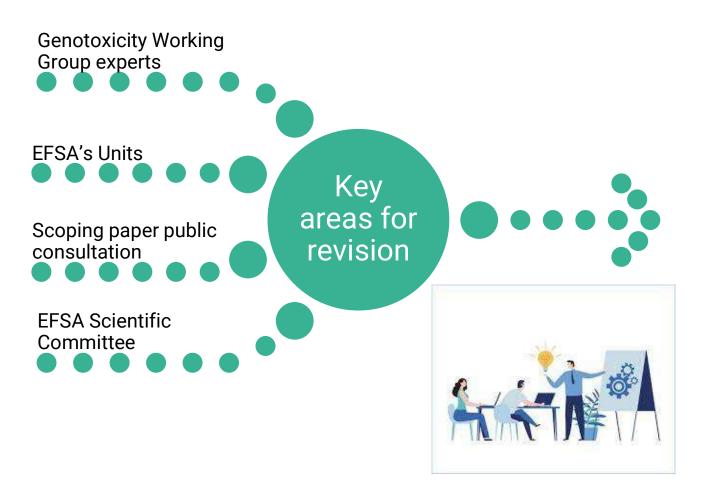
- Dissemination of the guidance via EFSA's channels and at conferences
- WG support for the application of the new guidance



GENOTOXICITY GUIDANCE REVISION STAKEHOLDER WORKSHOP, BRUSSELS 3 & 4 NOVEMBER



INPUT FOR THE GUIDANCE DEVELOPMENT



Stakeholder Workshop in Brussels

Physical meeting – 3 & 4
November 2025) to discuss
key aspects of the revision
and receive feedback from
relevant stakeholders
(industry, Member States,
NGOs, etc.)



PURPOSE OF THIS STAKEHOLDER WORKSHOP



- The **target audience and relevant stakeholders** of the Genotoxicity Guidance revision are risk assessors, risk managers, applicants, interested business operators (IBOs) and parties involved in the design and conduction of genotoxicity studies.
- Inform you about the on-going genotoxicity guidance revision and discuss key aspects and proposals developed by EFSA for the new guidance.
- Gather input and feedback on challenges you may have encountered related to the application of the current EFSA genotoxicity framework.
- Get ourselves informed about the state-of-the-art in genotoxicity assessment and new approaches that can be considered by the WG during the guidance development.
- With your input address specific questions on key aspects during the Breakout group session tomorrow.





THANK YOU!

