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).

- **General goal:** 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  - Target and Public Consultations of the draft guidance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 5 documents:

- 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

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.)

❖ 1: Main areas to be considered in guidance revision

❖ 2: New aspects to be included in the guidance

NEW GENOTOXICITY GUIDANCE KEY FEATURES

- The **revised and updated guidance** will be used by both applicants and risk assessors (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

Genotoxicity Working Group experts

EFSA's Units

Scoping paper public consultation

EFSA Scientific Committee

Key areas for revision

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!

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