

100TH ADVISORY FORUM
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REVISION OF THE EFSA BOTANICALS GUIDANCE – OVERVIEW & TIMELINES

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EFSA'S BOTANICALS GUIDANCE REVISION

The following **3 EFSA guidance documents** will be revised and merged into a single cross-cutting guidance concerning the assessment of botanicals and botanical preparations:

2009

Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements – 2-tiered framework (Level A/B)

2014

Scientific Opinion on a QPS approach for the safety assessment of botanicals and botanical preparations – 4-step structured assessment scheme

2023

Technical Report on Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials



RATIONALE FOR THE REVISION



Harmonisation needed

- Methodological inconsistencies across EFSA's sectoral approaches result in divergencies with regards to botanicals' safety assessment
- No internationally accepted guidance exists for botanical safety in food and feed

Guidance not fit for purpose

- The existing guidance is not supporting current needs
- Regulations like Novel Food Regulation (EU) 2015/2283 have introduced new assessment needs

Scientific advances

- NAMs, HRMS analytics, PBK modelling, new EFSA cross-cutting guidance
- EFSA's Compendium of Botanicals (updated 04/2025): Open-access database including hazard information on botanicals and substances of concern



EXPANDED SCOPE: ALL RELEVANT FOOD & FEED APPLICATIONS

2009 Botanicals Guidance

- Food supplements only
- "Can also be relevant" for other uses – but no specific guidance



Revised Botanicals Guidance

- Food supplements
- Novel foods
- Food enzymes
- Food additives
- Feed additives
- Food contact materials
- Pesticide active substances
- Art. 8 (Reg. (EC) No 1925/2006)



FRAMEWORK FOR SAFETY ASSESSMENT OF BOTANICALS - NEW

- a** Strengthened characterisation requirements (taxonomy, chemotype, Plants of the World online; POWO nomenclature)
- b** Tiered assessment to identify risk drivers, i.e., substances/groups of potential concern
- c** Systematic strategy for substances of concern (e.g., alkenylbenzenes, furanocoumarins)
- d** Matrix effects: when and how to consider bioavailability modulation
- e** Allergenicity assessment for botanical preparations



NAMS INTEGRATION & GUIDANCE ALIGNMENT



NAMs Integration

- In vitro assays (e.g., hepatotoxicity, neurotoxicity, cardiotoxicity)
- In silico tools: QSAR, PBK modelling & TK Plate
- Read-across for structurally similar constituents
- High-throughput (omics) screening methods

Cross-cutting Guidance Alignment

- TTC Guidance (SC, 2019)
- MixTox — combined exposure (SC, 2019)
- BMD modelling (SC, 2022)
- Read-across (SC, 2025)
- Also aligning with ongoing revisions: Margin of Exposure (MoE), evidence appraisal, Weight-of-Evidence (WoE) approach

Genotoxicity of botanical mixtures

Will refer to and align with EFSA's revised Genotoxicity Testing Strategy Guidance (expected Q2 2027), which will specifically address the genotoxicity assessment of botanicals and mixtures of natural origin.



TIMELINES & ENGAGEMENT ACTIVITIES

- Start of the work expected in **Q3 2026** for approximately 24 months
- **EFSA Panels:** NDA, FAF, FEEDAP, CONTAM, FEZ, FCM and Units dealing with botanical assessments – close coordination throughout the process
- **EU scientific bodies:** EMA, ECHA, JRC, SCCS – alignment and collaboration
- **International initiatives:** Botanical Safety Consortium (BSC), PARC – latest scientific developments on NAMs
- **Public engagement activities:**
 - 8-week Public Consultation on mandate paper
 - Stakeholder Workshop
 - Public Consultation on draft guidance
 - Info sessions and webinars



Public Consultation 08/06-03/08/2026

Comments welcome for the mandate paper:

- Terms of Reference
- Engagement activities
- Timelines

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THANK YOU!



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