EFSA Stakeholder Forum
Workshop
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INNOVATION IN FOOD RISK ASSESSMENT METHODOLOGY

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GUIDANCE ARCHITECTURE PORTFOLIO - OBJECTIVES

1. **Rebuild the process for the EFSA guidance lifecycle**
   - Need to enhance the predictability of the introduction of new methodologies
   - Need to clarify the interaction between cross-cutting and sectorial guidance documents

2. **Enhance guidance documents clarity, findability, usability**
   - Over 210 guidance documents
   - Published in different platforms (EJ, EFSA Supporting Publications, Zenodo, …)
   - As different output types (e.g. Statements, Technical Reports, …)
   - Status not always clear (obsolete/reviewed/updated/…)

3. **Increase the user friendliness and participatory nature to EFSA's methodological work**
   - Development of open and user-friendly tools for risk assessment

4. **Foster the harmonisation of risk assessment methods across EU and behind**

TIMELINE

Consultation on the main concepts with:

2024
Mapping of the current and envisioning the new architecture and processes

Q4 2024
Stakeholder Bureau
Stakeholder Forum

Q2 2025
EFSA Scientific Committee, Advisory Forum, European Commission, and Sister Agencies

Q3 2025
All stakeholders

Q1 2026
Consultation on the final Target Operating Model

GD CATEGORIES AND GOVERNANCE

Governance of Scientific GD

- Multiannual workplan for GDs
- Harmonisation and alignment
- Prioritisation and trigger for the development / revising of GD
- Seeking interest to co-create/co-revise

GD categories

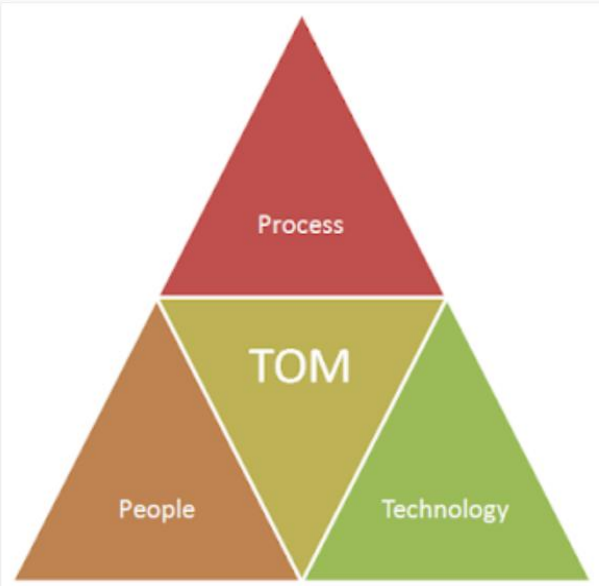
1. Cross-cutting GD [Scientific Committee]
2. Sector-specific GD for assessments other than regulated products [Scientific Panels]
3. Sector-specific GD for regulated products [Scientific Panels / EFSA]
4. Administrative GD for applications [EFSA]

GD content

a) the scientific assessment process conducted by risk assessors
b) study design and conduct (i.e., data requirements, when not specified in the regulation)
c) data submission

GD LIFECYCLE AND TARGET OPERATING MODEL (TOM)

Phase 1: GD Initiation	Phase 2: GD Development or Revision, publication, dissemination				Phase 3: GD Implementation and monitoring			Phase 4: GD Review
Step 1 →	Step 2 →	Step 3	Step 4 →	Step 5 →	Step 6	Step 7 →	Step 8 →	Step 9
GD initiation (for new GD or GD under revision)	Preliminary activities to GD Dev or Revision	GD Dev or Revision	Def of implement ation plan	GD Publication & Dissemination	Transition period	Capacity building	GD implementati on and monitoring	GD Review Communication of review outcomes



PROCESS ORGANISATION

Special attention to:

- Definition of an implementation plan
  - Integration of cross-cutting GD per the sector-specifics
  - Testing / piloting with real use cases
- Mechanism of engagement per guidance category and phase
- Capacity building and training material
- Development of tools for risk assessment to facilitate the use of new methodologies
- Monitoring of GD
  - Continuous collection of feedback on GD use (e-logbook).

THE CATALOGUE OF EFSA GD

- The catalogue of Guidance documents is currently under development
- It is intended to enhance guidance documents findability within a single place
- Information in the catalogue could be consulted:
  - as such and/or
  - through the application webpages with predefined dashboards
- Accessible through Power BI in the short/medium term
- Integrated into Appian/Open EFSA in the long term
- It could evolve into an EU Library of GD

NEW WAY OF PUBLISHING EFSA GUIDANCE DOCUMENTS

Guidance documents should be more clear, flexible, interactive and searchable.

GD Category	Revisions and Versioning	Impact and visibility
Cross-cutting GD	Versioning control and a high level of flexibility in relation to minor and major updates. All versions should be clearly visible and easily accessible and superseded versions should be clearly identified as such.	The **main target** of this GD are risk assessors within and outside EFSA, **Visibility** (e.g. indexation in databases) could be an important requirement
Sector-specific GD for assessments other than regulated products		
Sector-specific GD for regulated products		The **main target** of this GD are applicants, a wide **visibility** (e.g. indexation in databases) is not an important requirement.

ENGAGEMENT WITH EXTERNAL PARTIES

Engaging with the actors of the food safety ecosystem plays a key role in EFSA's operating model.

Highly participative

Inform

- Raising awareness on and/or explaining a scientific output to a target group of partners and stakeholders

Consult

- One-off elicitation of feedback from partners and stakeholders (e.g., on a draft (interim) scientific output)

Collaborate

- EFSA-led development of a scientific output informed through regular and systematic involvement of third parties in several steps of the mandate

Co-own

- Joint development, co-adoption and implementation of the same output by a subset of co-authoring partners.

Examples of possible engagement mechanisms and tools

Inform

- Targeted or public dissemination
- Targeted or public informative meetings, in person or online
- Presentation at existing EFSA's communities (e.g., Advisory Forum, MS Networks, etc.)
- Presentation at third-party meetings (e.g., scientific conferences)
- Videorecorded webinars, FAQs, infographics, …

Consult

- Written targeted or public consultations / surveys / calls for views
- Targeted or public dialogue-based meetings (e.g., technical meetings, workshops, focus groups)
- Technical hearings of EFSA's scientific Working Groups and Panels

Collaborate

- Ad-hoc discussion platforms (e.g., thematic discussion groups) following a call for expression of interest
- Partnership agreements and scientific cooperation mechanisms

Co-own

- Joint mandate to the co-authoring organisations (e.g., from the EC)
- Coordination Working Group of the co-authoring organisations
- Mutual participation in the respective Experts Working Groups of the co-authoring organisations

GUIDANCE ON NANOPARTICLES RISK ASSESSMENT

Self-task mandate proposed by the Scientific Committee to develop an updated '***Guidance document for risk assessment of nanomaterials and materials containing nanoparticles in the food chain***' (M-2024-00062)

The update should be structured in three steps and engagement activities are foreseen during all phases:

Phase 1
- By **30/06/2026**: focus to merge the existing GDs and clarify structure and requirements

Phase 2
- By **30/12/2027**: focus on major scientific updates

Phase 3
- By **30/12/2029**: focus to incorporate results from the NAMs4NANO Project (Lot 1-2-3)

Engagement activities

GUIDANCE ON NANOPARTICLES RISK ASSESSMENT

Proposed plan of engagement for phase 1 guidance update

Q4 2024 - Q1 2025: Call for views on the mandate objectives and Terms of Reference

Q4 2024 - Q2 2026:
Development of the Guidance

Q2 2025:
Scoping document outlining proposed structure and key elements of the updated Guidance

Q2 2026:
Publication of the merged EFSA Guidance (phase 1 update)

Open for feedback from **regulators & stakeholders**

Open for feedback from **regulators & stakeholders** on structure and key elements, also via ad hoc meetings and workshop

Ad hoc meetings with regulators (e.g. bilaterals) & stakeholders (e.g. technical hearings)

Open for feedback from **regulators & stakeholders** on new scientific developments for phase 2

GUIDANCE ON BIOMARKERS OF EFFECT

Self-task mandate proposed by the Scientific Committee on a new "**Guidance on the use of biomarkers of effect in regulatory risk assessment of chemicals**" (M-2023-00097)

- The development was split in two phases:

Phase 1

- By the **end of 2024**: Feasibility study (Scientific Report)

Phase 2

- **2025-2026**: Development of outline and draft guidance
- **From 2026**: Development of OECD guidance

Engagement activities

GUIDANCE ON BIOMARKERS OF EFFECT (PHASE 2)

Proposed plan of engagement

2024:
Discussion and agreement with EU Agencies and EC on the mandate.

2025
Develop the **Guidance outline**

Project proposal to OECD

2026
Approval of the OECD project

2026
Adoption of a **draft Guidance** by EU Agencies

Transfer the draft Guidance to OECD

2026 - ?
OECD Guidance development

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