GMO NETWORK

UPDATE ON ACTIVITY *'TAKING STOCK OF ~30 YEARS OF EXPERIENCE IN RISK ASSESSMENT EVALUATIONS OF GM PLANTS'*

Stakeholders meeting

25 March 2026

efsa
EUROPEAN FOOD SAFETY AUTHORITY

TIMELINE - 19TH GMO NETWORK MEETING – 5-6 JUNE 2025

- 19th GMO Network meeting – 5-6 June 2025 - Warsaw, Poland
  - Preliminary presentation of the Belgium initiative - Item 11 - ***Taking stock of ~30 years of experience in risk assessment evaluations of GM plants – a topic for the Scientific Network?***
  - Belgium's overview of nearly 30 years of GMO risk assessment (RA), from the first dossiers in the 1980s–1990s to current practices
  - International developments shaping RA approaches:
    - Canada (2022): introduced a tiered information-requirements approach for "retransformants" using previously assessed DNA sequences.
    - Japan (2014): adopted a 3-category system for stacked events, with data requirements depending on trait complexity and metabolic impact.

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TIMELINE - 19TH GMO NETWORK MEETING – 5-6 JUNE 2025

- **Proposed initiative**: develop a structured questionnaire to collect experiences and practices from EU Member States on RA of GM plants for import and processing.
- Objectives of the Belgium initiative:
  - Improve scientific efficiency and consistency of RA across the EU
  - Promote harmonisation of methodologies and data requirements
  - Support global alignment of GMO risk assessment approaches
  - Identify key RA actors in each MS and track how RA practices evolved over time
- GMO Network support: Participants agreed on the initiative and on developing the questionnaire, and to revisit the topic in future meetings.

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TIMELINE - 20TH GMO NETWORK MEETING – 24 NOVEMBER 2025

- **Belgium** presented a preliminary overview of the activity
- Feedback collected from **17 countries** (**19 institutes**) (June – October 2026) indicates that accumulated practical experience in GM risk assessment is not yet fully reflected in current evaluation approaches.
- **Single events**:
  - Waiving data requirements for familiar traits (e.g., Cry proteins).
  - Limiting extensive dietary exposure assessments and conducting 90-day rat toxicity studies only when a clear risk hypothesis is identified.
- **For stacked events**:
  - full risk assessments may be unnecessary when single events have already been positively evaluated.
  - Case-by-case focus on plausible trait interactions.
  - Discussion on whether NEP expression levels in stacks should be assessed when they may differ from single events.
  - Suggestion that compositional studies/field trials may not be required if no interaction hypothesis exists.

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NEXT STEPS

- EFSA reminded participants of the ongoing discussion with the cross-cutting Working Group and the GMO Panel, which was also mentioned at the last GMO Panel meeting open to observers.
- Network members to confirm consent for sharing questionnaires internally.
- Agreement to continue discussions, with a proposed focus on stacked event risk assessment.
- Need for scientifically substantiated rationale when proposing reduced data requirements.

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