

AD hoc meeting with
industry representatives
5-6TH October 2023

GMO GUIDANCE DOCUMENTS



GMO APPLICATIONS

Regulatory framework

Scientific guidance

Administrative guidance

Tools



SCIENTIFIC GUIDANCE - LIST ON THE WEBSITE TILL MARCH

- <https://www.efsa.europa.eu/en/applications/gmo/regulationsandguidance>

Before March:

- 22 scientific documents, not sorted

Scientific guidance

Applicable to all applications (submitted before or after 27 March 2021)

- [Guidance on risk assessment of food and feed from GM plants](#)
- [Human dietary exposure assessment to newly expressed proteins in GM foods](#)
- [Explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin](#)
- [Guidance on allergenicity assessment of genetically modified plants](#)
- [Explanatory note on literature searching conducted in the context of GMO applications](#)
- [Technical Note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants](#)
- [Explanatory note on DNA sequence similarity searches](#)
- [Explanatory note on the determination of newly expressed protein](#)
- [Environmental risk assessment of GM plants](#)
- [Guidance on the agronomic and phenotypic characterisation of genetically modified plants](#)
- [Guidance for renewal applications of genetically modified food and feed authorised under Regulation EC 1829/2003](#)



SCIENTIFIC GUIDANCE - LIST ON THE WEBSITE FROM APRIL

- <https://www.efsa.europa.eu/en/applications/gmo/regulationsandguidance>

Now:

- Grouped per organism and subsector
- Created dependencies (main guidance → follow-up guidance → explanatory or technical note on specific topics)
- Updated (four documents deleted, four added: statement 90-day, ADE, GMM FEEDAP, WGS)

GM Plants – Molecular characterisation and food/feed

Main guidance

- 2011: [Guidance on risk assessment of **food and feed** from GM plants](#)

Molecular characterisation

- 2018 [Explanatory note on the determination of **newly expressed protein** levels in the context of genetically modified plant applications for EU market authorisation](#)
- 2018 [Technical Note on the **quality of DNA sequencing** for the molecular characterisation of genetically modified plants](#)

Food/feed safety

- 2014 [Explanatory statement for the applicability of the Guidance of the EFSA Scientific Committee on conducting repeated-dose **90-day oral toxicity study** in rodents on whole food/feed for GMO risk assessment](#)
- 2017 [Guidance on **allergenicity** assessment of genetically modified plants](#)
- 2019 [Human dietary exposure assessment to newly expressed proteins in GM foods](#)
- 2022 [Animal dietary exposure in the risk assessment of feed derived from genetically modified plants](#)

Comparative assessment

- 2011 [Guidance on the selection of **comparators**](#)
- 2015 [Guidance on the **agronomic and phenotypic** characterisation of genetically modified plants](#)

NEXT ACTIVITIES

Administrative Guidance

- CC list update
- Data/application driven, lean, with scenarios
- *Benefits:*
 - *Improve newly submitted dossier (by new applicants in particular)*
 - *Possible reduction in number of ADRs*

Scientific Guidance

- Compilation of guidances
- Not touching the content
- Joint effort of staff and experts
- *Benefits:*
 - *Identify priority areas/ADR for review*
 - *Integration with future guidance documents*
 - *Periodic (5-year) review more feasible*



NEXT GMO PANEL ACTIVITY

- Prepare a unified scientific guidance for the risk assessment of GM plants integrating scientific content developed after 2011 avoiding duplication and conflicts
- Provide recommendations for the improvement of administrative guidance for GMO applications

(To be started at the beginning of 2024)



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