GMO GUIDANCES

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LIST ON THE WEBSITE TILL MARCH

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

- 22 Scientific Guidances in total
- 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

LIST ON THE WEBSITE FROM APRIL

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

- Grouped per organism and subsector
- Created dependencies (main guidance with later follow-up detailed guidances on specific topics
- 4 deleted (opinion allergenicity, opinion NTO, opinion statistics, report animal feeding trials)
- 4 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

BETTER USE OF GUIDANCE - SUGGESTIONS

Why

- WIN for EFSA: better dossiers – faster RA due to less ADRs
- WIN for Applicants: less ADRs

How

- What can EFSA do?
  - E.g. Make critical appraisal tools based on the CC-checklists?
- What can applicants do?

When

- Are there burning needs for updates?
- Wait till EC mandates

ANY OTHER FEEDBACK TO BE RECORDED DURING THE MEETING

- Include checklists and data models (when relevant) in guidance documents?
- Guidance to be EFSA publications discussed and endorsed (when relevant) by the GMO panel?
- Assess recurrent additional data requests to define needs of guidance updates?

- …
- …

- Please provide any input ahead or during the meeting so that we discuss it
- Purpose is for EFSA staff to reflect what can be done. Thanks!

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