



# Review of risk assessment methodology for RNAi-based GM plants

Ad-hoc meeting with GMO applicants

8/04/2024

## PROJECT AIMS

**EFSA's objectives:** in order to update EFSA's guidance documents, the scientific literature is regularly reviewed and the RA methodologies are updated, if needed, to follow the progress in knowledge in the field; EFSA provides support for the applicants in order to harmonise data submission and reduce risk assessment time

Literature searches to determine the need for update of EFSA's strategy for the RA of RNAi-based GM plants

Bioinformatic tool delivered by EFSA to the applicant to harmonise plant RNAi off-target searches



# PROJECT TIMELINE

Project start: December 2022

Literature search start: January 2023

Milestone review: Q3 2023

Project end: Q3 2024



# GUIDANCE DOCUMENT ON RNAI-BASED GM PLANTS

- Legal basis: [Commission Implementing Regulation 503/2013](#), section 1.2.2.3 (e)
- Based on previous EFSA work: [Pačes et al., 2017](#), [Dávalos et al., 2019](#), [Papadopoulou et al., 2020](#) and literature search from 2017 onwards
- To supersede [Annex II to the 118<sup>th</sup> GMO Panel meeting minutes](#)
- Areas to be covered: molecular characterisation, dietary exposure
- **To be published at the end of 2024**



# BIOINFORMATIC TOOL FOR PLANT RNAI OFF-TARGETS

- A script to be used for the IR 503/2013-required dsRNA off-target analysis, in plants
- The analysis will not be performed in EFSA environment
- To be run by the applicants; independent of EFSA submission tools
- Outcome will not be known/stored in EFSA; is owned by the applicant
- The result to be analysed by the applicant and submitted in the respective study with the GMO application dossier
- To be made available through an open-source repository
- **First version of the script to be made available for applicants' feedback at the beginning of May**



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