



4. UPDATE FROM EFSA UNITS ON GMO APPLICATIONS RA AND GLP STUDIES



Ad hoc meeting with GMO Industry Representatives

25 March 2026



GMO APPLICANT MEETING

25 MARCH 2026

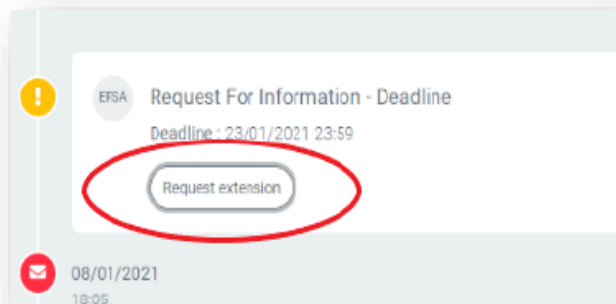


Risk Assessment Logistics
Unit

ADDITIONAL DATA REQUEST – DEADLINE EXTENSION



Submit your extension request via ESFC, not via e-mail, providing a detailed justification



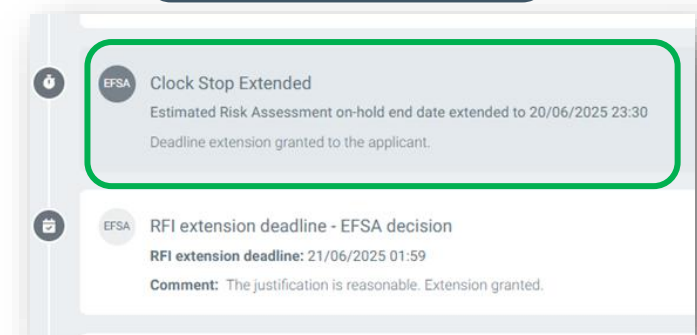
EFSA assesses the request

First and second extension request
Assessed based on applicant's justifications

Third extension request granted only if requested before the deadline expiration and due to reasons beyond applicant's control



Approved extensions are displayed in the timeline



ADDITIONAL DATA REQUEST – NO REPLY



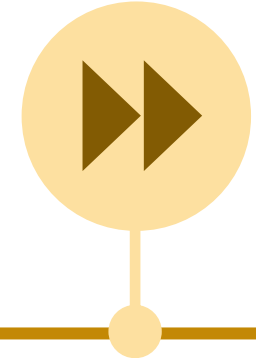
Automatic
ESFC
notification



Automatic
ESFC
notification



Final
reminder



If no reply is submitted,
EFSA resumes the risk
assessment and the
respective Panel will
finalize its Opinion
based on the available
information.

The applicant has the right
to withdraw and submit a
new application when all
missing data are available.

ADDITIONAL DATA REQUEST – REPLY



Replies must be uploaded in the relevant dossier sections. Should you need to update previously provided information, leave the original submission unchanged and upload a new document replying to the questions posed.



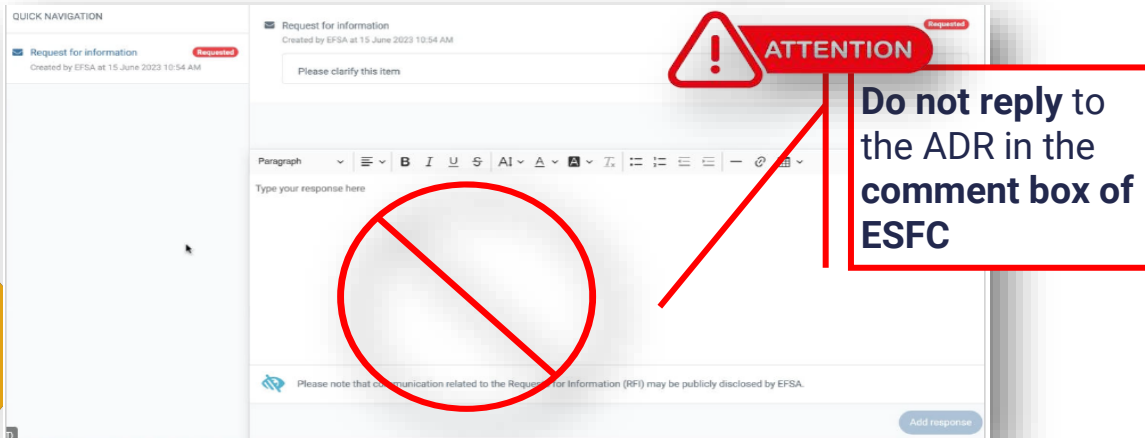
EFSA checks the completeness of the reply and can issue a follow-up ADR.



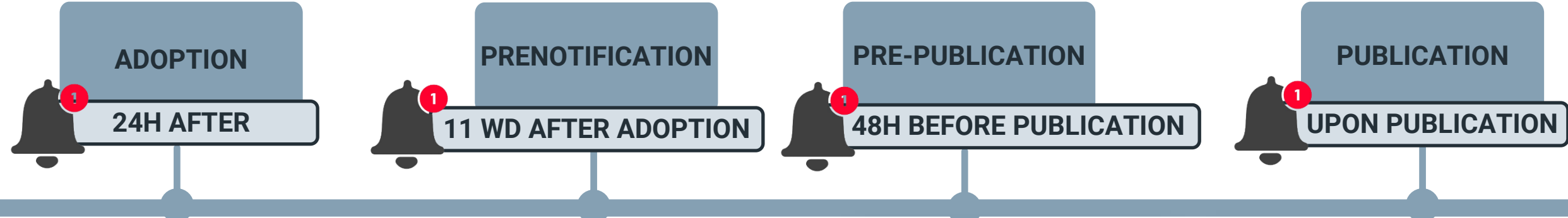
EFSA checks the reply to the follow-up ADR (if applicable).



EFSA resumes the RA. The clock-stop end-date will be the one of the complete submission.



PUBLICATION TIMELINE



Dossier Overview

EC Risk Management

17/10/2024 11:50

EFSA Opinion Adopted
Output Adoption Date: 16 Oct 2024

03/10/2024 11:32

EFSA Publication Pre-Notification

View Opinion

Comment Deadline
12 September 2025 11:00 AM

Opinion to be Published

File link
File link
File link

EFSA Opinion

Expected publication date
15 September 2025 11:00 AM

Dossier Overview

07/10/2024 11:13

EFSA Output Published

View Opinion

4 WORKING DAYS DEADLINE FOR COMMENTS

- DO'S**
- Comment on confidentiality matters
 - Signal objective inaccuracies
- DON'TS**
- Signal typographical errors (the Opinion will undergo typesetting prior to publication)
 - Submit new confidentiality requests
 - Send attachments
 - Ask for a deadline extension



RISK ASSESSMENT CONSIDERATIONS FOR RNAI-BASED GENETICALLY MODIFIED PLANTS



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 recent literature findings
- Superseded [Annex II to the 118th GMO Panel meeting minutes](#)
- Areas covered: molecular characterisation, dietary exposure
- **Published at the beginning of 2025:**
<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2025.932>

1



3.1.1 PARAMETERS FOR IN SILICO SEARCH FOR PLANT ENDOGENOUS OFF-TARGET TRANSCRIPTS

The applicants will be requested to **report on possible off-target plant transcripts complying with all the following rules** for all 21nt small RNAs potentially produced:

(...)

The transcriptome of the GM plant species (the most up-to-date version available) should be used for off-target searches. Moreover, the **search should also be performed on all newly expressed transcripts in the event** (either single or stack) under assessment. If it is not feasible to perform an off-target search on all newly expressed transcripts, the applicant should provide a supplementary theoretical analysis, considering the likelihood of novel transcript formation and its potential impact on off-target silencing based on known mechanisms of RNAi.



3.1.2 CONSIDERATIONS ON HOW THE RESULTS SHOULD BE DISCUSSED

The RA of the potential off-target gene silencing in the plant should be based on:

- The number of different small RNAs showing significant similarity to the same potential off-target transcript. The potential for repression of a gene by a small RNA is correlated with the number of different small RNAs that can bind the same transcript (Hannus et al., [2014](#)).
- Off-target **transcripts with multiple hits should be the prime focus** of the assessment. However, in GMP applications where a single small RNA is produced at high abundance (e.g. production of artificial miRNA), a single off-target sequence within a transcript may also be of relevance.
- The established or predicted function of the potential off-target genes and their potential impact on the safety of the GM plant and/or derived products as food/feed and for the environment





UPDATED PMEM PLAN

UPDATED PMEM PLAN

- CompERA WG (January 2024) recommended to provide detail on the methodology proposed for the General Surveillance of PMEM plans
- Agreement reached in June 2026
- Annex with Additional information on usual measures of operators to limit the exposure of the environment to the GM crop in the context of General Surveillance
- Applicants are encouraged to submit the updated PMEM plan including Annex for all running APs & RXs
- Avoid sending ADRs





CONTRACTOR'S REPORTS

ISA SCHEME AND PROCUREMENT CONTRACTS

Areas of RA: Literature searches, Sequencing quality, Bioinformatics, Statistical analysis of in vivo studies

- Deliverables provided by contractors as preparatory work for the risk assessment, can be shared with applicants, once EFSA acquires the ownership of the results for the use and sharing of the reports.
- The ownership of the deliverables is acquired once the payment of the service has been concluded, according to the provisions present in each contract (ISA-Article 10, Direct and FWC- Article I.10)
- If the reports cannot be shared upon the publication of the scientific opinion, they will be shared soon afterwards.





UPDATE ON GLP STUDIES

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- **Info on GLP requirements and acceptance of GLP studies in application dossiers**
 - EFSA GLP webpage ([link](#))
 - GMO Administrative guidance documents
 - Previous GMO applicants' meetings (19/03/2025 & 30/10/2025)
- **In case of ad hoc study audit request during completeness check**
 - Validity of application on hold till GLP monitoring authority confirms GLP status of study/ies



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