



# UPDATE FROM FDP UNIT ON POST-TR GMO DOSSIERS

**CLAUDIA PARISI**

EFSA GMO ad hoc meeting with applicants  
08/04/2024

# POST-TR GMO DOSSIERS OVERVIEW

- 27 March 2021: implementation of the Transparency Regulation (Reg. (EU) 2019/1381)
- 34 post-TR GMO dossiers have been received so far, starting in May 2022:

## GM PLANTS:

- 9 new single events
- 3 new stacked events
- 18 renewals: 3 in 2022 and 15 (+3) in 2024

## GM MICROORGANISMS:

- 4 new applications in parallel with FEED

## Note on 2024 GMO renewal applications:

So far, EFSA received 15 renewal dossiers in 4 weeks.

As exceptional measure for internal work distribution, CC/validation dates might be anticipated in some renewal applications.

- A simplified ToC for e-submission of GMO applications (new/renewal), valid for all organisms, is in place since November 23<sup>rd</sup> 2023.





# RESPONSE TO EFSA REQUESTS FOR INFORMATION (RFI)

## RECOMMENDATIONS TO REPLY TO RFI:

- Please, integrate the missing information into the corresponding documents of the dossier or in the metadata of each document, as applicable.
- Using the free-text box that opens when you reply to the EFSA request (available in each section of the ESFC platform) indicate the changes made with a **brief description of the new information provided**.

# LETTERS OF ACCESS (LOA)

EFSA legal services were recently consulted about the use of **Letters of access (LoA)** in post-TR dossiers, instead of confidential and non-confidential version of particular files. Main points:

- It is the responsibility of the applicant to provide all the data necessary for risk assessment (Art. 4(3) of Reg. 1829/2003)
- LoAs allow an applicant to use information for which a previous applicant had ownership (Art. 31 of Reg. 1829/2003).

## HOWEVER:

- LoAs do not exempt the applicant from submitting that data in the application.
- EFSA shall make public, upon validation, all non-confidential dossiers and carries out a public consultation on the studies received (GFL Art. 38(1)c, 39b(1)a and 32c).

EFSA cannot accept a **single event** dossier that includes only LoA instead of a confidential and a non-confidential version of the corresponding studies/documents.

## SPECIAL CASE:

- GM crops with **stacked events**: In accordance with IR (EU) No 503/2013, for the risk assessment of those events the applicant can refer to already submitted application(s).

# STAY CONNECTED

## SUBSCRIBE TO

[efsa.europa.eu/en/news/newsletters](https://efsa.europa.eu/en/news/newsletters)  
[efsa.europa.eu/en/rss](https://efsa.europa.eu/en/rss)  
[Careers.efsa.europa.eu](https://careers.efsa.europa.eu) – job alerts



## LISTEN TO OUR PODCAST

Science on the Menu – Spotify, Apple Podcast and YouTube



## FOLLOW US ON TWITTER

[@efsa\\_eu](https://twitter.com/efsa_eu)                      [@methods\\_efsa](https://twitter.com/methods_efsa)  
[@plants\\_efsa](https://twitter.com/plants_efsa)                [@animals\\_efsa](https://twitter.com/animals_efsa)



## FOLLOW US ON LINKEDIN

[Linkedin.com/company/efsa](https://linkedin.com/company/efsa)



## FOLLOW US ON INSTAGRAM

[@one\\_healthenv\\_eu](https://instagram.com/one_healthenv_eu)



## CONTACT US

[efsa.europe.eu/en/contact/askefsa](https://efsa.europe.eu/en/contact/askefsa)

