



## **CORRESPONDENCE DURING THE LIFE-CYCLE OF A GMO DOSSIER (RISK ASSESSMENT AND PUBLICATION PHASES)**

**AD HOC MEETING WITH GMO  
INDUSTRY REPRESENTATIVES  
19 MARCH 2025**

Alessia Amodio  
Risk Assessment Logistics Unit



## WHAT'S ON THE MENU

1

Risk assessment phase

2

Post-adoption phase

3

Tracking a valid dossier  
in ESFC

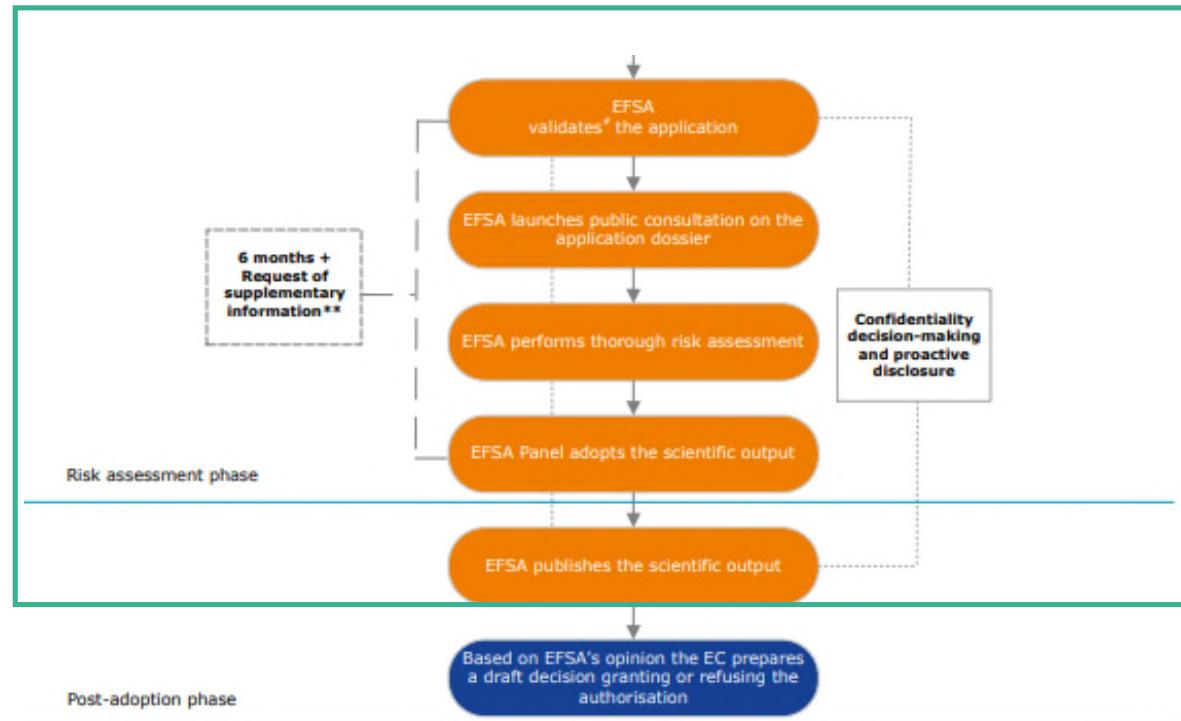
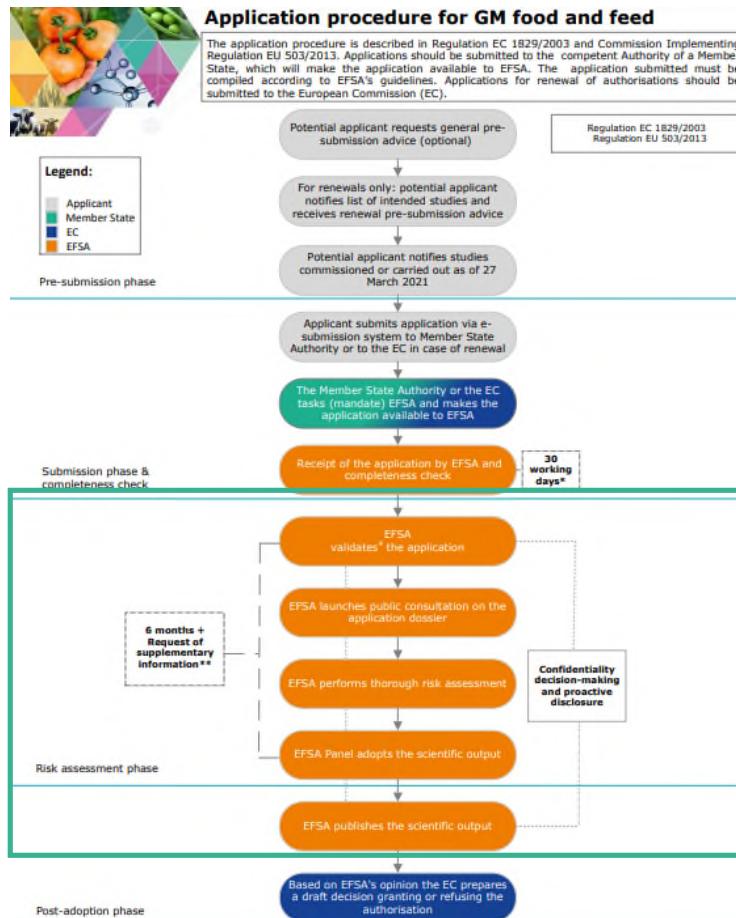
4

Tracking a valid dossier  
in OpenEFSA

Q&A



# APPLICATION PROCEDURE FOR GM FOOD AND FEED



\*\*In case of a request for additional information, the scientific risk assessment process is put on hold until the requested additional information is supplied by the applicant

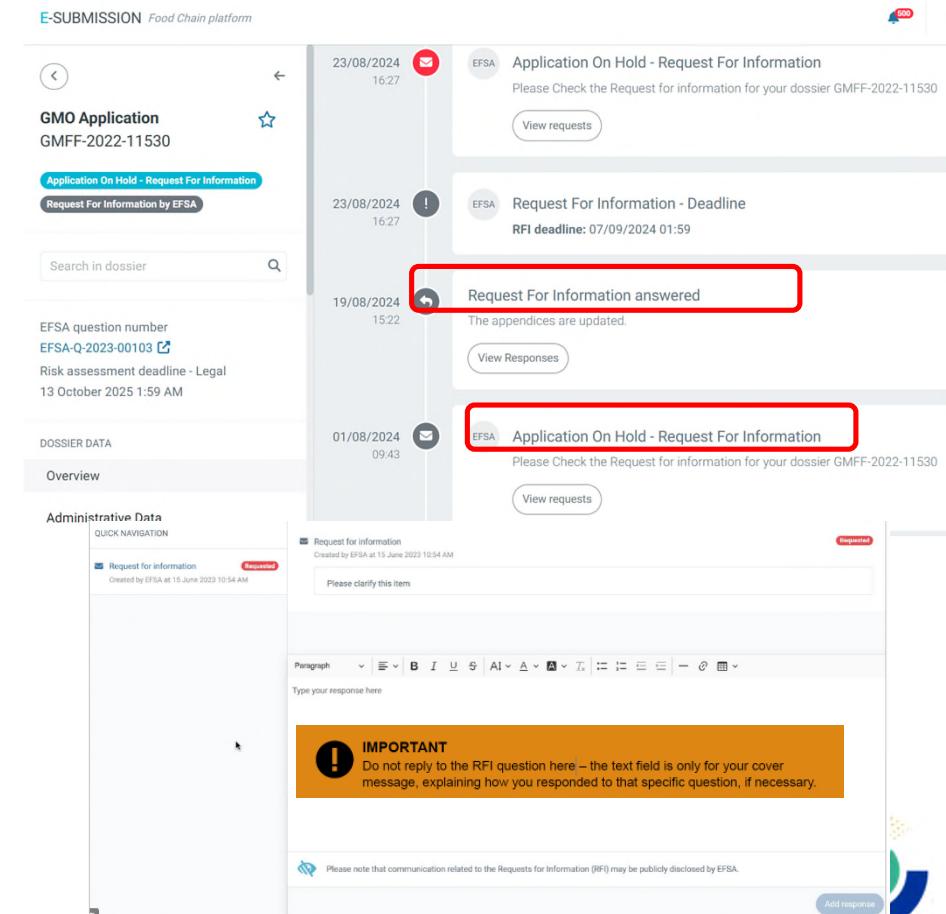
<https://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflowgmo.pdf>



# RA PHASE – ADDITIONAL DATA REQUEST (ADR)

- Named **RFI** in the ESFC tool
- Deadline displayed in the request
- **RA put on hold and RA deadline extended**
- To be considered during RA, **replies** must be **integrated** in the technical dossier text and/or annexes and/or metadata of the documents (no need to highlight the changes)
- **Do not reply** using the **comment/reply box of ESFC**
- New submitted studies are subject to **NOS obligations**
- After evaluation of the received information, if this is complete, the **RA is restarted as of the date of receipt**

In case of **technical issues** in the ESFC tool  
contact the ESFC help desk:  
[sante-e-submission-food-chain@ec.europa.eu](mailto:sante-e-submission-food-chain@ec.europa.eu)



The screenshot shows the E-SUBMISSION Food Chain platform interface. On the left, a sidebar displays a 'GMO Application' with the identifier 'GMFF-2022-11530'. It shows 'Application On Hold - Request For Information' and 'Request For Information by EFSA'. Below this is a 'DOSSIER DATA' section with an 'Overview' and an 'Administrative Data' section containing a 'Request for information' entry. The main area is a timeline of events:

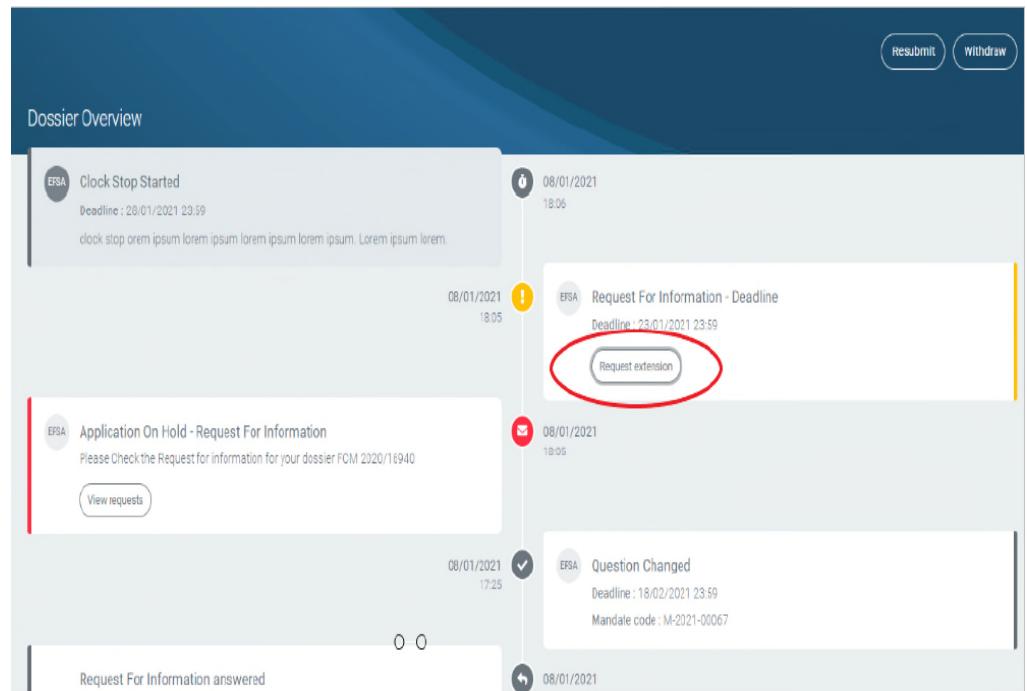
- 23/08/2024 16:27: EFSA - Application On Hold - Request For Information. Message: 'Please Check the Request for information for your dossier GMFF-2022-11530'. A 'View requests' button is present.
- 23/08/2024 16:27: EFSA - Request For Information - Deadline. Message: 'RFI deadline: 07/09/2024 01:59'. A 'View Responses' button is present.
- 19/08/2024 15:22: EFSA - Request For Information answered. Message: 'The appendices are updated.' A 'View Responses' button is present. This entry is highlighted with a red box.
- 01/08/2024 09:43: EFSA - Application On Hold - Request For Information. Message: 'Please Check the Request for information for your dossier GMFF-2022-11530'. A 'View requests' button is present. This entry is highlighted with a red box.

At the bottom, a large text input field is labeled 'Type your response here'. A yellow 'IMPORTANT' box contains the text: 'Do not reply to the RFI question here – the text field is only for your cover message, explaining how you responded to that specific question, if necessary.' Below the input field, a note states: 'Please note that communication related to the Requests for information (RFI) may be publicly disclosed by EFSA.' A blue 'Add response' button is located at the bottom right.

More information on ADR can be found in section 2.11 of the [Administrative guidance for the processing of applications for regulated products](#)

# RA PHASE – REQUESTING ADR DEADLINE EXTENSION

- Submit your deadline request **via ESFC**, not via e-mail
- Provide a **detailed justification** to the new deadline
- EFSA will assess if the extension is acceptable and, if so, approve it
- Extension request is displayed in the timeline



## RA PHASE - PARALLEL ADR

ESFC does not allow to submit a new ADR (parallel ADR) if the previous one (first ADR) is not completed



1. EFSA sends the **parallel ADR via e-mail**, with clear explanation of the process



2. APPLICANT responds to the first ADR via ESFC



3. Clock remains stopped and EFSA re-send the **parallel ADR via ESFC**



4. APPLICANT responds to the parallel ADR via ESFC



## RA PHASE – CLARIFICATION TELECONFERENCE

A **clarification teleconference** can be requested – via e-mail to the Head of the NIF unit - to:

- ❖ clarify scientific rationale of individual questions raised and of additional information requested during the risk assessment;
- ❖ ensure understanding of the questions and of the request for additional information to be answered by the applicant.



**Clarification teleconferences are not meant to provide pre-assessment of upcoming applicant responses**

More information on clarification teleconferences can be found in section 2.3.1 of the [EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#)



## RA PHASE – SPONTANEOUS SUBMISSION OF INFORMATION

**Spontaneous information** (not requested by EFSA) can be submitted to provide:

- ❖ newly produced data; and/or
- ❖ information which was not available at the time of the submission of the application.

- Submission shall occur as early as possible during RA, accompanied by an explanation about how it may influence the risk assessment

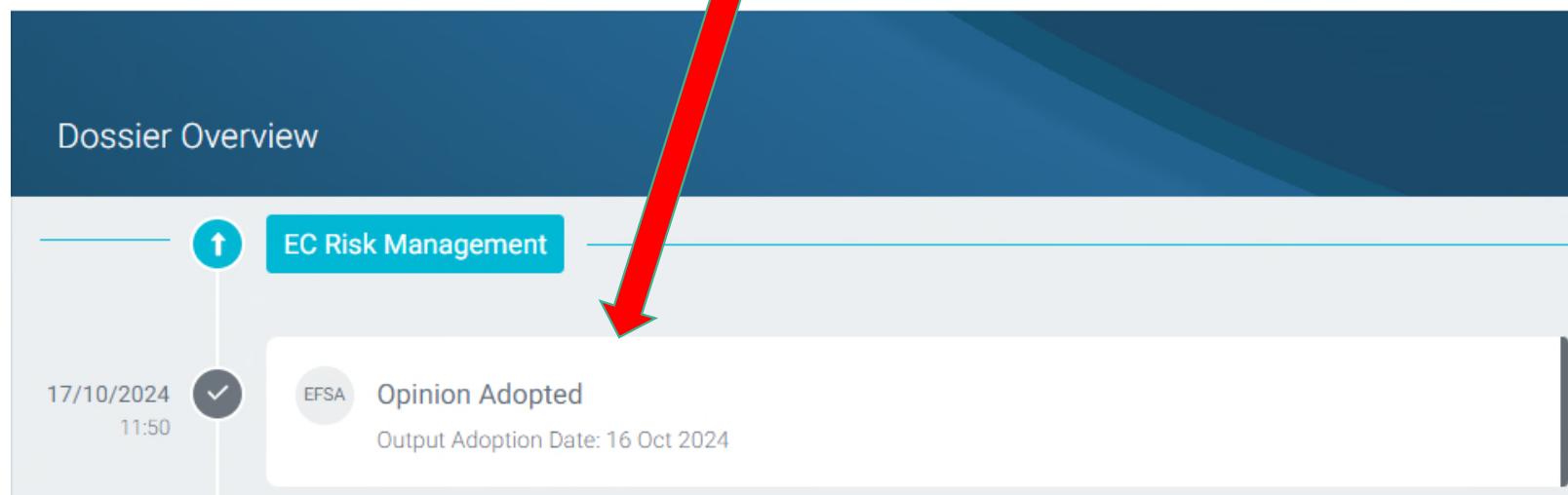
To submit spontaneous information and have the relevant sections open in ESFC  
contact

[RAL@efsa.europa.eu](mailto:RAL@efsa.europa.eu)



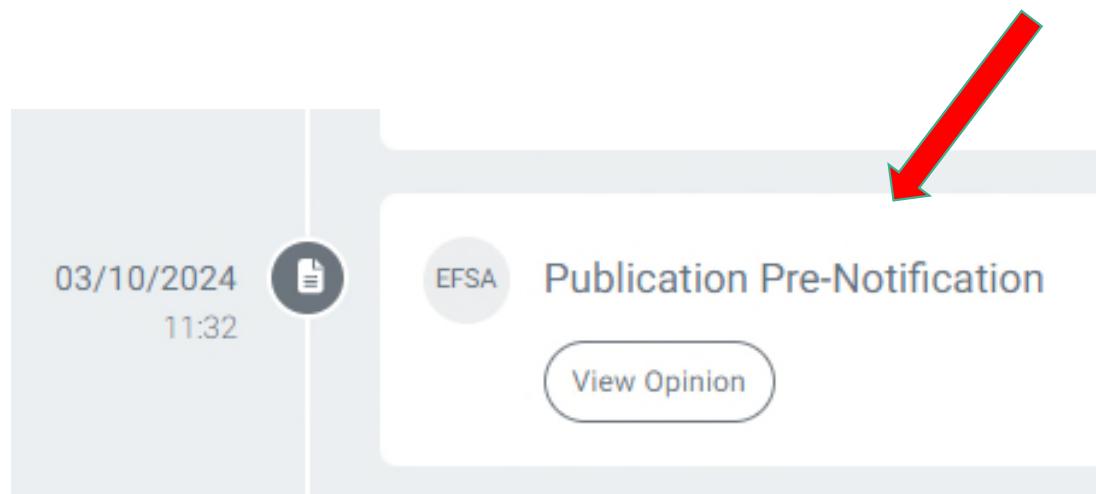
# POST-ADOPTION PHASE – NOTIFICATION UPON ADOPTION

EFSA Scientific Opinion adopted → ESFC notification



# POST-ADOPTION PHASE – PRE-PUBLICATION NOTIFICATION

- **ESFC Notification informing about the imminent publication** (scientific opinion shared **under embargo**)
- At least **36 hours** before publication
- The pre-notification message serves as a **communication tool** to inform the applicant of the outcome of the risk assessment



# POST-ADOPTION PHASE – NOTIFICATION UPON PUBLICATION

Scientific Opinion published → ESFC notification informing about the publication in the [EFSA Journal](#)

The image shows a screenshot of the EFSA Dossier Overview and the EFSA Journal website. On the left, the 'Dossier Overview' page for GMFF-2022-9170 is displayed, showing the date 26/04/2024, 11:12, and a 'View Opinion' button. A red arrow points from this button to the 'Link to publication' section on the right. On the right, the 'EFSA Journal' page for the same dossier is shown, featuring the journal logo, 'OPEN ACCESS', and the title 'Assessment of genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 and 8 out of 10 of its subcombinations for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2022-9170)'. Another red arrow points from the 'Link to publication' section on the left to this journal page, illustrating the notification process.

## POST-ADOPTION PHASE – POST-ADOPTION TELECONFERENCE

A **post-adoption teleconference** can be requested – **via e-mail to the NIF Head of Unit** – to:

- ❖ explain the scientific rationale of the final output from the Panel and/or EFSA;
- ❖ clarify the recommendations of the scientific output (if applicable);
- ❖ clarify the sources of evidence and the factors that influenced the outcome.



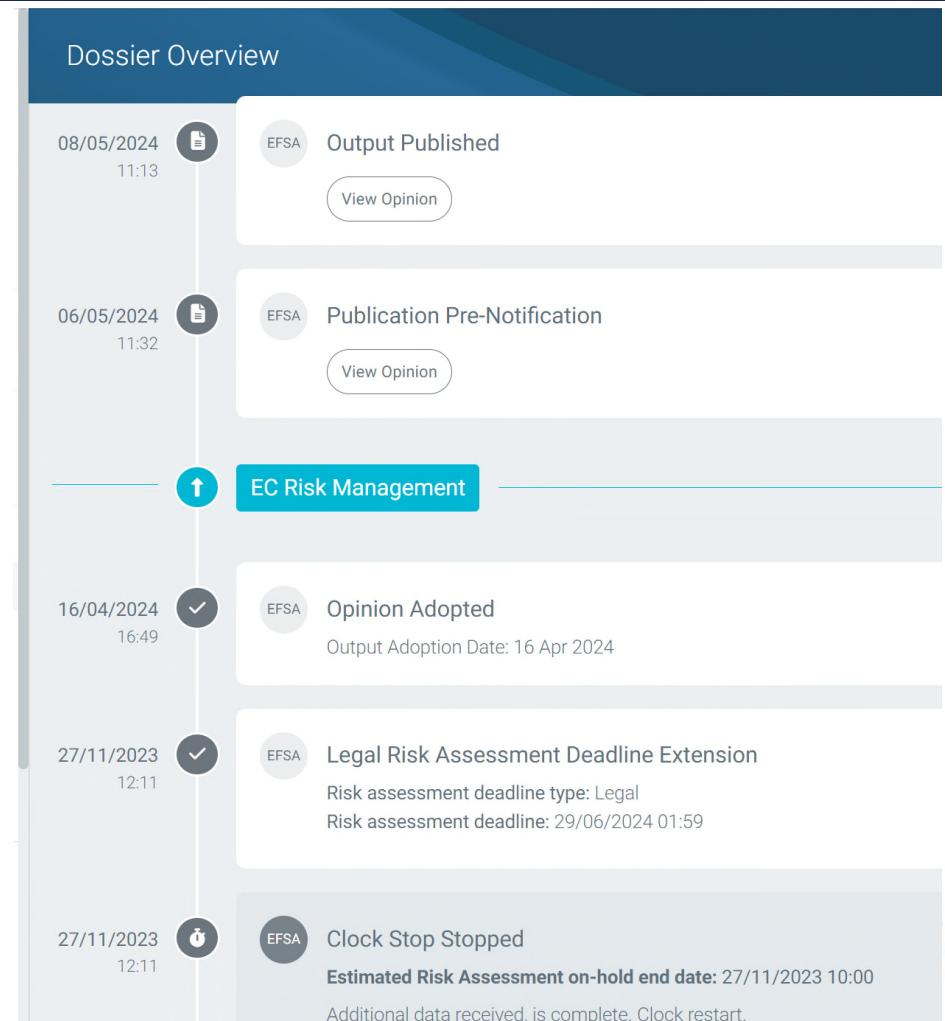
**Post-adoption teleconferences are not meant to provide any scientific advice for future submissions**

More information on post-adoption teleconference can be found in section 2.4.3 of the [EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#)



# TRACKING A VALID DOSSIER - ESFC

- **E-submission Food Chain platform (ESFC)** one-stop-shop to follow the progress of the dossier
- The dashboard timeline will update as the dossier proceeds through each stage of the risk assessment:
  - Additional data request (ADR) / Clock-stop
  - ADR deadline extension
  - Risk Assessment (RA) deadline extension
  - Adoption
  - Publication Pre-notification
  - Output publication



More information on ESFC can be found in the [EFSA Toolkit](#)

# TRACKING A VALID DOSSIER - OPEN.EFSA

GMO

## Food and Feed - Regulation (EC) No 1829/2003

EFSA-Q-2022-00845 | Status: Published

Last updated: 29/04/2024

### Subject

Application for renewal of genetically modified MON 89034 x 1507 x MON 88017 x 59122 maize and part of its subcombinations in accordance with Regulation (EC) No. 1829/2003 (RX027)

### Output

Output Number: ON-8715  
Output Type: Scientific Panel or Committee  
Publication Date: 29/04/2024  
View published version of the output: See details

### Supporting documents

Document Type	Download file
Additional Data Request	<a href="#">PDF (183.3KB)</a>
EC Mandate	<a href="#">PDF (92.0KB)</a>
Additional Data Request	<a href="#">PDF (145.8KB)</a>
Notification of Studies	<a href="#">PDF (106.9KB)</a>

### Risk Assessment Deadline Extension

The risk assessment deadline has been updated due to a clock stop event type End. The risk assessment deadline has been updated due to a clock stop event type Start

### Timeline

03-06-2024 Risk Assessment Deadline

29-04-2024 Output Published

13-03-2024 Output Adopted

From 19-12-2023 to 05-02-2024

Clock Stop

Additional data request #1

Administrative Data - Cover letter

Technical Dossier - Information to support the Risk Assessment - New Information- Systematic search and evaluation of literature

Requested on: 19/12/2023

Answered on: 05/02/2024

2024

See detailed timeline

### General Info

Dossier number  
GMFF-2022-9170

Applicants  
Corteva Agriscience  
Mandate number  
M-2022-00201



OpenEFSA

All you need to know about our risk assessments

Dedicated portal hosting comprehensive information on our risk assessments, from receipt of a mandate or dossier to adoption of an output: check the status of assessments, browse data and studies, and details about experts.

### Timeline: EFSA-Q-2022-00845

03-06-2024 Risk Assessment Deadline

29-04-2024 Output Published

13-03-2024 Output Adopted

From 19-12-2023 to 05-02-2024

Clock Stop

Additional data request #1

2024

From 22-08-2023 to 12-12-2023

Clock Stop

Additional data request #1

From 28-07-2023 to 18-08-2023

Application for renewing the authorisation for the placing on the market of the genetically modified MON 89034 x 1507 x MON...

• market of the genetically modified MON 89034 x 1507 x MON...

Public Consultation Finished

See details

14



More information on Open EFSA can be found in the [EFSA Toolkit](#)



## USEFUL TO KNOW!



<https://www.linkedin.com/groups/9083910/>



<https://www.efsa.europa.eu/en/applications/about/services>



<https://connect.efsa.europa.eu/RM/s/help>



THANK YOU FOR  
YOUR ATTENTION

