



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**

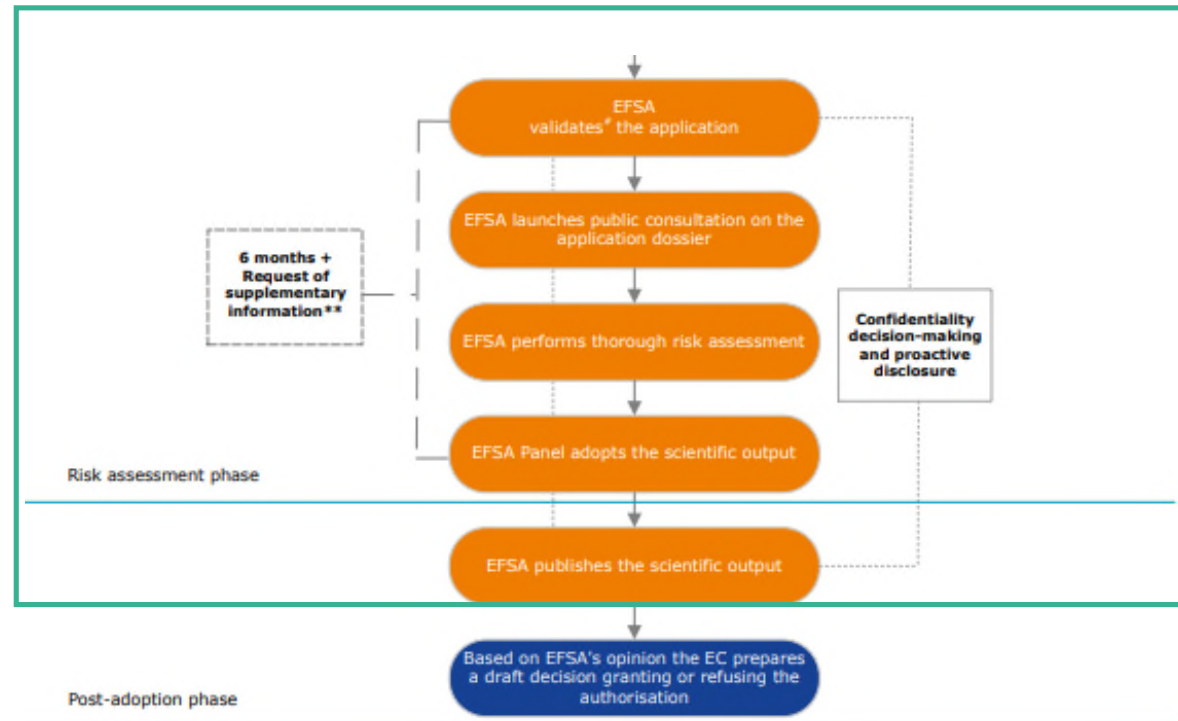
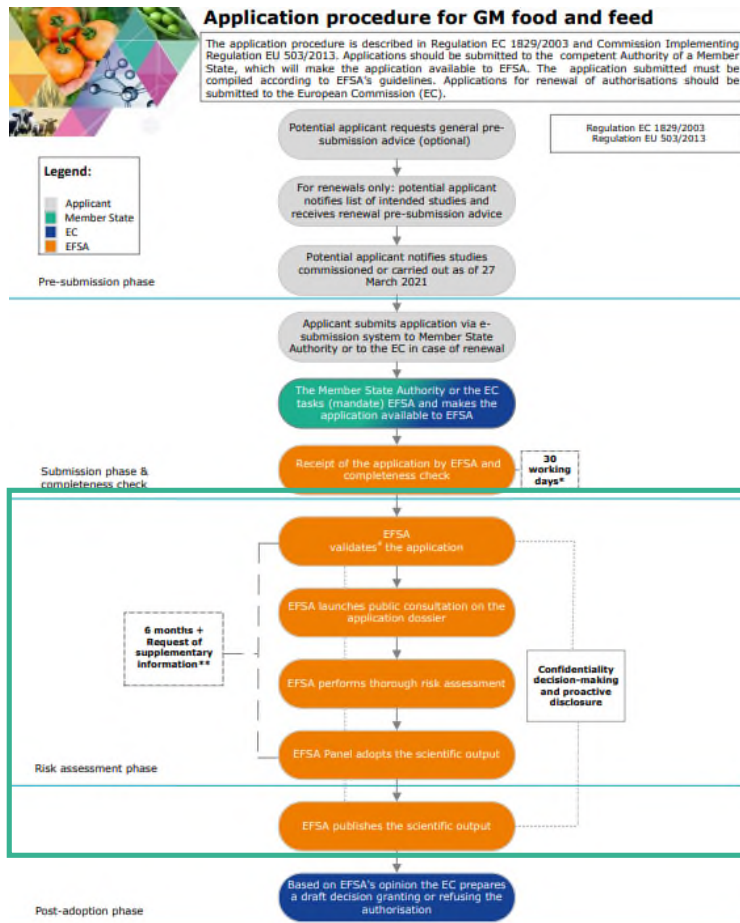
4

**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)

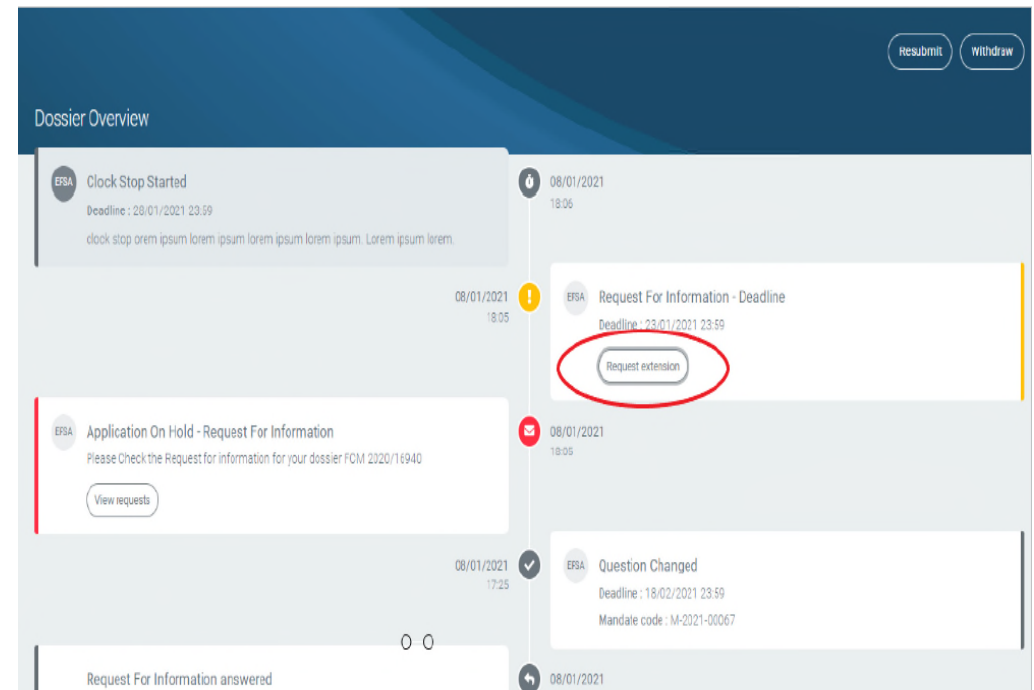
- Named **RFI** in the ESFC tool
- Deadline displayed in the request
- **RA put on hold** and **RA deadline extended**
- To be considered during RA, **replies** must be **integrated** in the technical dossier text and/or annexes and/or metadata of the documents (no need to highlight the changes)
- **Do 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

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



POST-ADOPTION PHASE – NOTIFICATION UPON ADOPTION

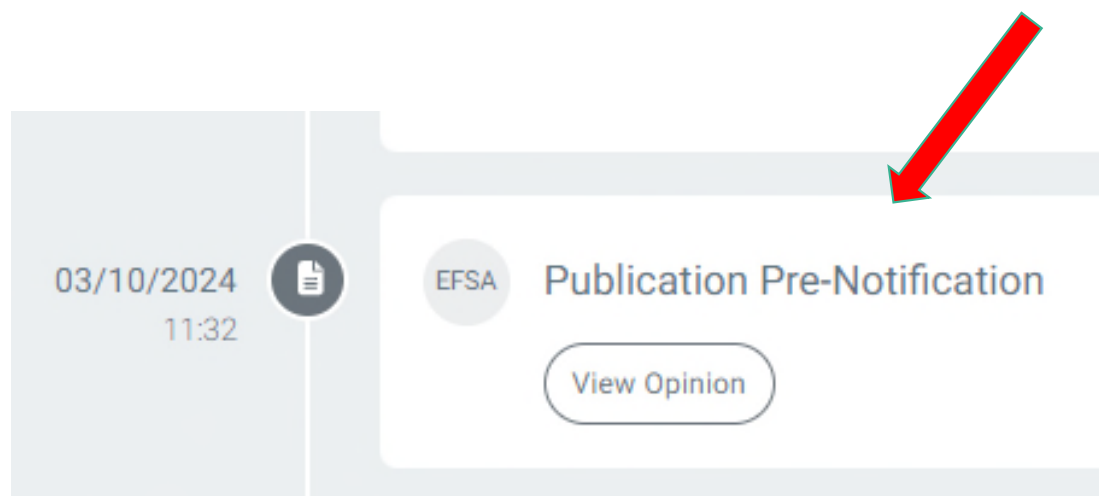
EFSA Scientific Opinion adopted → **ESFC** notification

The screenshot displays a 'Dossier Overview' interface. At the top, there is a dark blue header with the text 'Dossier Overview'. Below this, a light blue bar contains an upward arrow icon and the text 'EC Risk Management'. A red arrow points from the text 'EFSA Scientific Opinion adopted → ESFC notification' to this 'EC Risk Management' section. Below the bar, a timeline shows a date '17/10/2024' at '11:50' with a checkmark icon. To the right of this, a white box contains the text 'EFSA Opinion Adopted' and 'Output Adoption Date: 16 Oct 2024'.



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**

GMO Application
GMFF-2022-9170

Opinion Adopted Risk Management by EC

Search in dossier



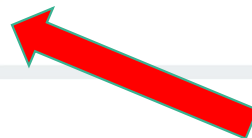
Dossier Overview

26/04/2024
11:12



Output Published

View Opinion



GMO Application
GMFF-2022-9170

Opinion Adopted Risk Management by EC

Search in dossier



EFSA Opinion

Link to publication

File link
26 April 2024 11:12 AM



EFSA Library

Search

Login / Register

JOURNALS

SUBJECTS

efsa.europa.eu



SCIENTIFIC OPINION | Open Access | CC BY-NC-ND

Assessment of genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2022-9170)

EFSA Panel on Genetically Modified Organisms (GMO). Ewen Mullins, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M. Epstein, Leslie George Firbank ... See all authors

First published: 29 April 2024 | <https://doi.org/10.2903/j.efsa.2024.8715>

Adopted: 13 March 2024

Annexes 1-8 are available under the Supporting Information section.

SECTIONS



PDF



TOOLS



SHARE

Abstract

Following the joint submission of dossier GMFF-2022-9170 under Regulation (EC) No



Volume 22, Issue 4
April 2024
e8715



References



Related



Information

Recommended

[Assessment of genetically modified maize MON 88017 for renewal authorisation under Regulation \(EC\) No 1829/2003 \(application EFSA-GMO-RX-014\)](#)

EFSA Panel on Genetically Modified Organisms (GMO). Hanspeter Naegeli, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M. Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatk, Evgenia Ivleva-Moreira, Ewen Mullins

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

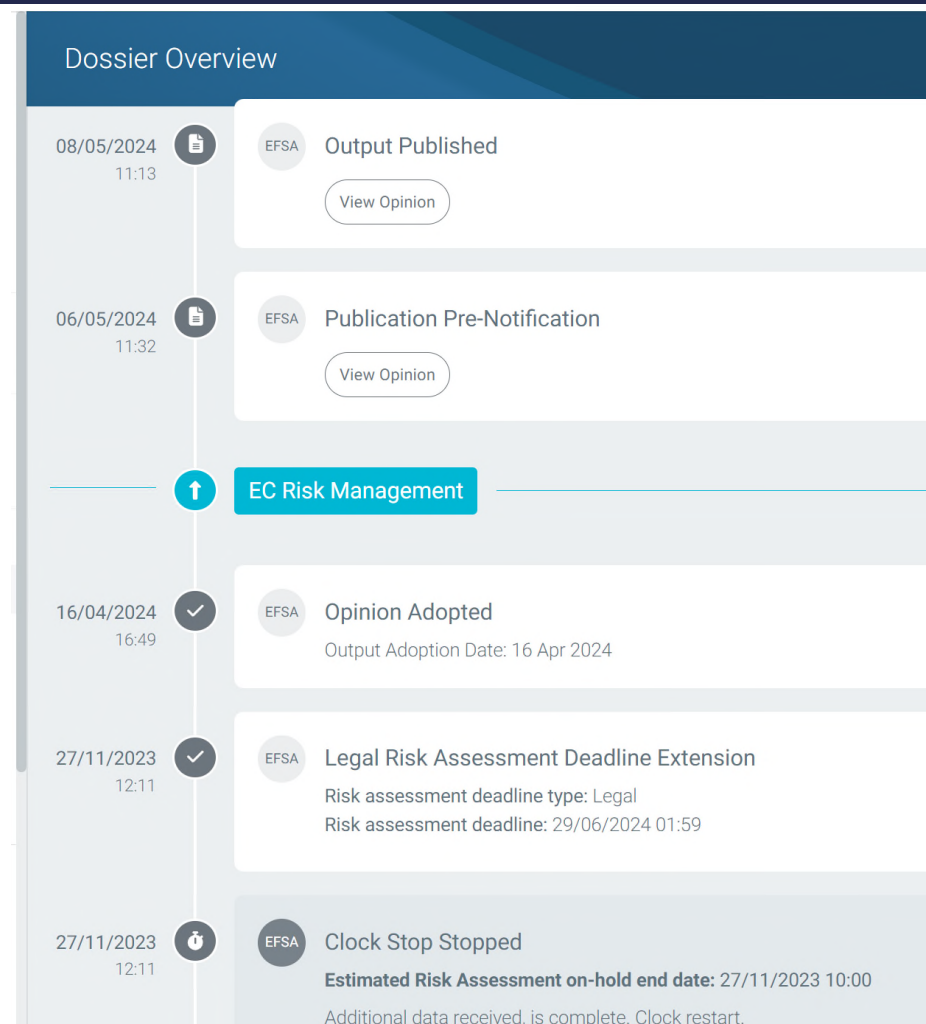
More information on post-adoption teleconference can be found in section 2.4.3 of the [EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products](#)



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



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.

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

All files

Document Type	Download file
Additional Data Request	PDF (183.3KB)
EC Mandate	PDF (92.0KB)
Additional Data Request	PDF (145.8KB)
Notification of Studies	PDF (106.9KB)

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



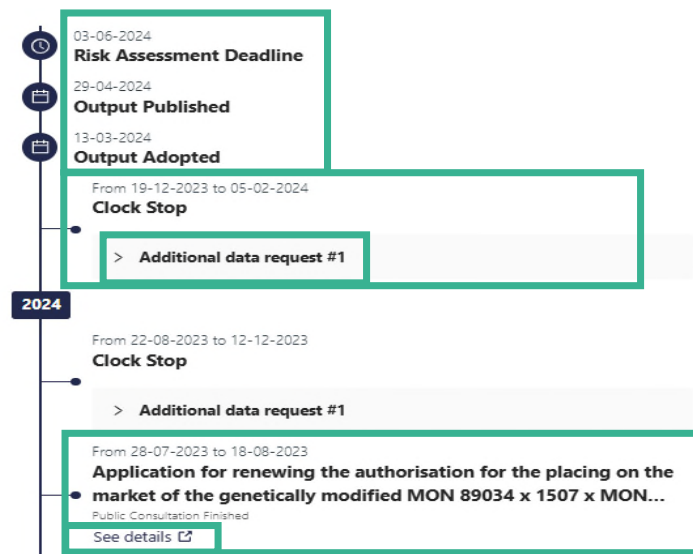
[See detailed timeline](#)

General Info

Dossier number
GMFF-2022-9170

Applicants
Corteva Agriscience
Mandate number
M-2022-00201

Timeline: EFSA-Q-2022-00845





**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**

