

CORRESPONDENCE DURING THE LIFE- CYCLE OF AN ENZYME DOSSIER (**RISK ASSESSMENT AND PUBLICATION PHASES**)

Technical meeting on applications for food enzymes
24 October 2024

Risk Assessment Logistics (RAL) Unit



WHAT'S ON THE MENU

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Risk assessment phase

2

Post-adoption phase

3

**Tracking a valid dossier
in ESFC**

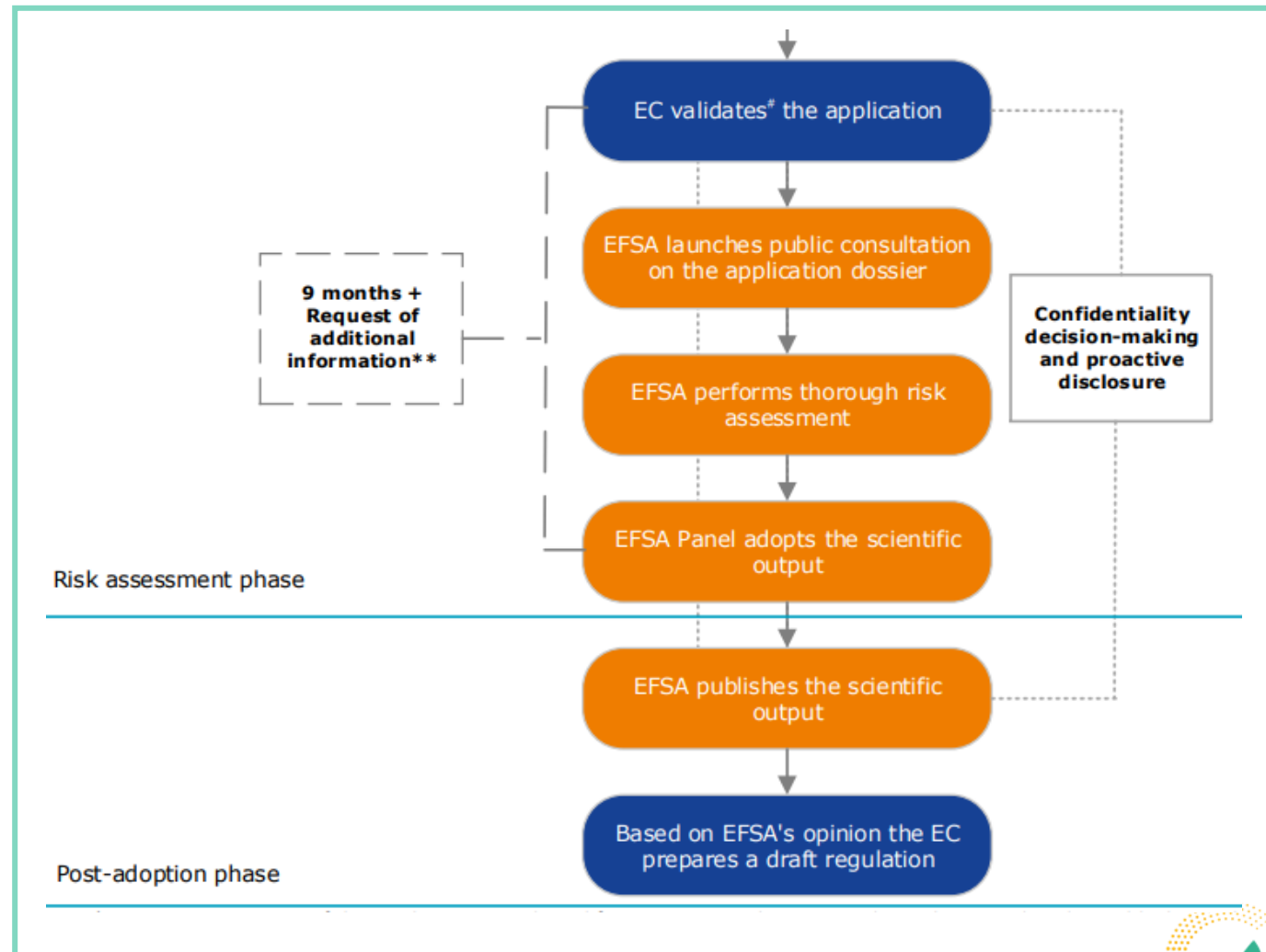
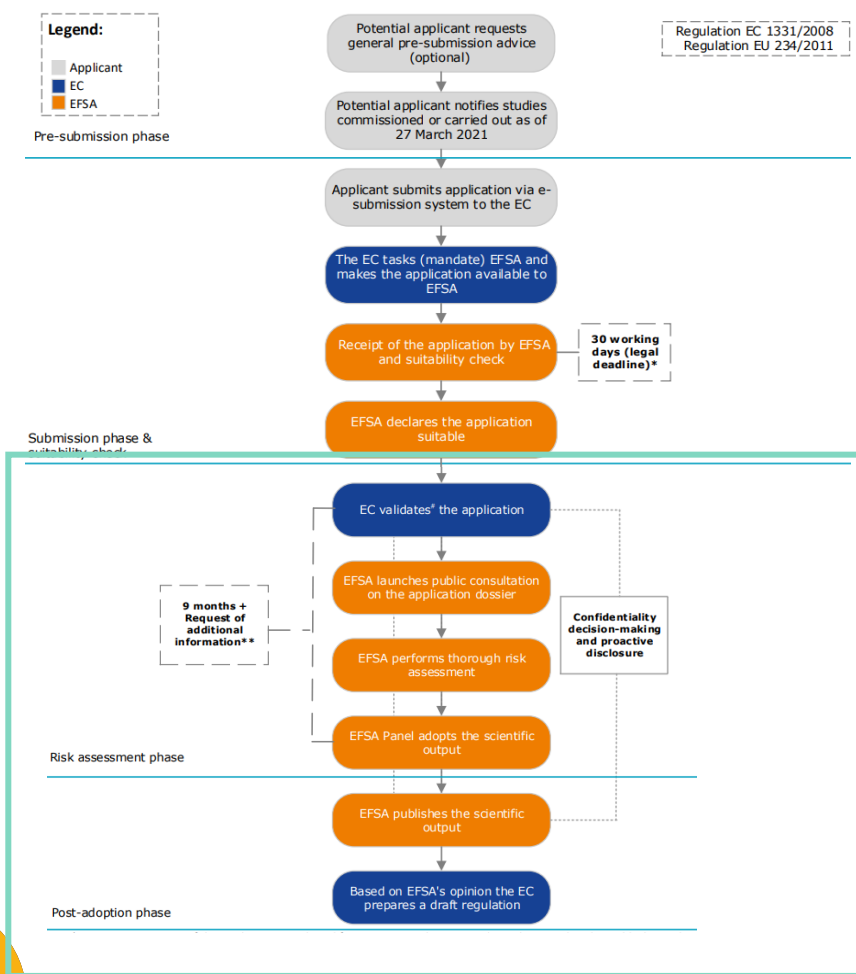
4

**Tracking a valid dossier
in OpenEFSA**

Q&A



FOOD ENZYMES' APPLICATION PROCEDURE



*In case certain parts of the application need modification or completion to be considered suitable, the applicant receives a request to provide missing information

In certain cases, the application might be declared as non-valid (see EFSA administrative guidance for further information)

**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



RA PHASE – **ADDITIONAL DATA REQUEST**

During the risk assessment phase, EFSA may request the applicant to submit **additional information**

- Deadline specified in the request
- **RA put on hold & RA deadline extended**
- **Replies** must be **integrated** in the technical dossier text and/or annexes and/or metadata of the documents, otherwise they will not be considered during risk assessment (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 receipt of the additional information the **RA is restarted**
- If you **have technical issues** in ESFC: write to ESFC help desk (sante-e-submission-food-chain@ec.europa.eu)

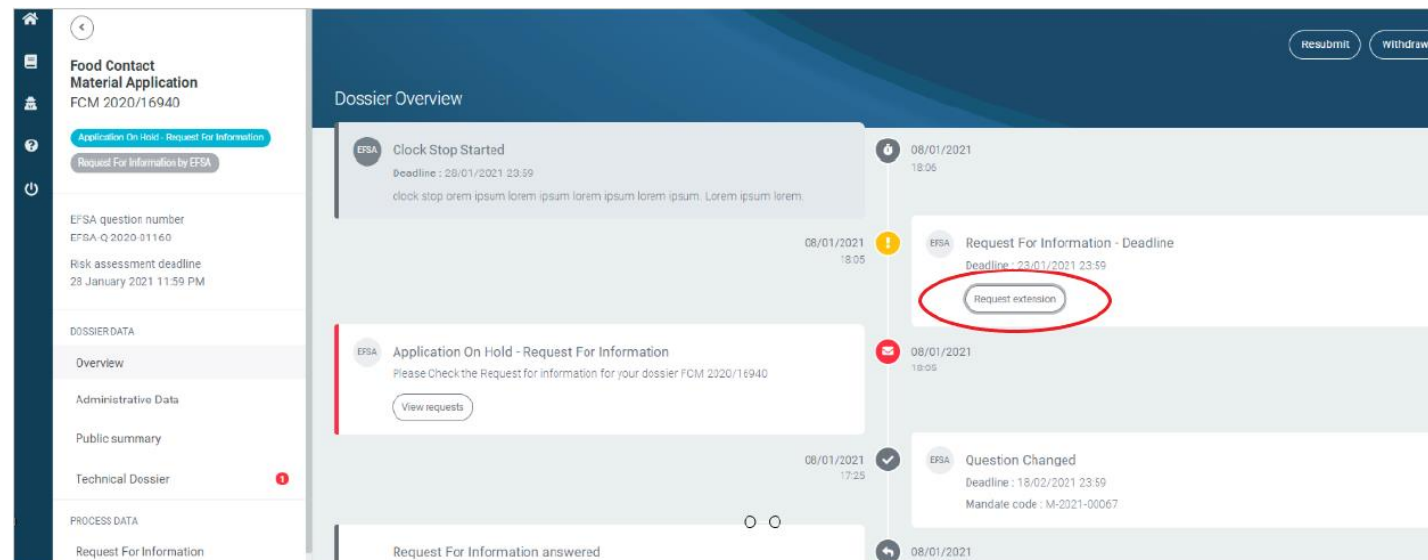
The image displays two screenshots from the EFSA E-SUBMISSIONS portal. The top screenshot shows the 'Dossier Overview' for a 'Food Contact Material Application' (FCM 2020/16940). It highlights a 'Request for Information - Deadline' (09/01/2021) and an 'Application On Hold - Request For Information' (09/01/2021). A red circle highlights the 'Request for Information' status. Below this, a 'Request for Information' (RFI) form is shown, titled 'Request for Information FCM 2020/16940 Food Contact Materials'. The form includes a 'Dear user,' message and a request for additional information. The bottom screenshot shows the 'RFI for Characterisation of the food additive(s) / Identification of substance(s)' form. It includes a 'Request for Information' section with a 'Please clarify this item' field and a 'Type your response here' section. An 'IMPORTANT' notice states: '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.'

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 DDL EXTENSION

The **ADR deadline** may be **extended** at the request of the applicant:

- Request to be submitted via the e-submission system
- Detailed justification of the new proposed deadline should be provided
- EFSA will decide on the acceptability of the extension request
- Extension reflected in the timeline



RA PHASE – FOOD ENZYMES ADRS' IN NUMBERS

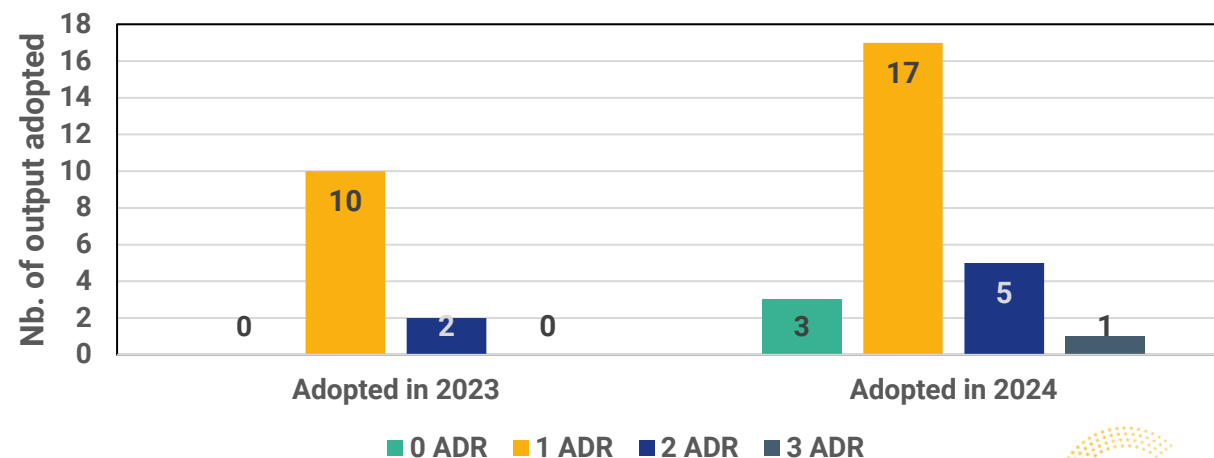
Additional Data Request (ADR)

- 🕒 **83 ADRs** sent for 68 EFSAQs
- 🕒 **12 ADR deadline extensions** requested (average ~ 4.5 months)

Questions Adopted

Post-TR  **38**

Nb. of ADR requested per output adopted



RA PHASE – CLARIFICATION TELECONFERENCE

- **What:** After receiving a request for additional information or clarifications by EFSA and before submitting the response, the applicant can ask EFSA to organise a teleconference to clarify the questions raised by EFSA
- **How to request the service:** e-mail to the Head of the relevant scientific unit
- **Scope:** The clarification teleconference is organised in case a request for additional/supplementary information by EFSA is not clear to the applicant. This teleconference can be requested to:
 - i) clarify scientific rationale of individual questions raised and of additional information requested during the risk assessment;
 - ii) ensure understanding of the questions and of the request for additional information to be answered by the applicant.
- Clarification teleconferences do not provide pre-assessment on upcoming responses to be submitted by the applicant.



RA PHASE – SPONTANEOUS SUBMISSION OF DATA

The **spontaneous submission of information by an applicant** on its own initiative and without a formal request for information by EFSA is **possible but limited to**:

- newly produced data; and/or
 - information which was not available to the applicant at the time of the submission of the application.
-
- Spontaneous information should be submitted as early as possible during the risk assessment process, and the applicant should explain how it may influence the risk assessment.
 - The spontaneous information should be provided through the e-submission system **exclusively following preliminary contact with RAL** (RAL@EFSA.europa.eu).



POST-ADOPTION PHASE – NOTIFICATION UPON ADOPTION

EFSA Opinion adopted:

- What: a notification informing about the **adoption of the opinion**
- When: **after adoption**

E-SUBMISSION *Food Chain platform*



Food Improvement
Agents Application
FEN-2022-10691

Opinion Adopted

Risk Management by EC

Search in dossier



Dossier Overview



EC Risk Management

17/10/2024
11:50



EFSA

Opinion Adopted

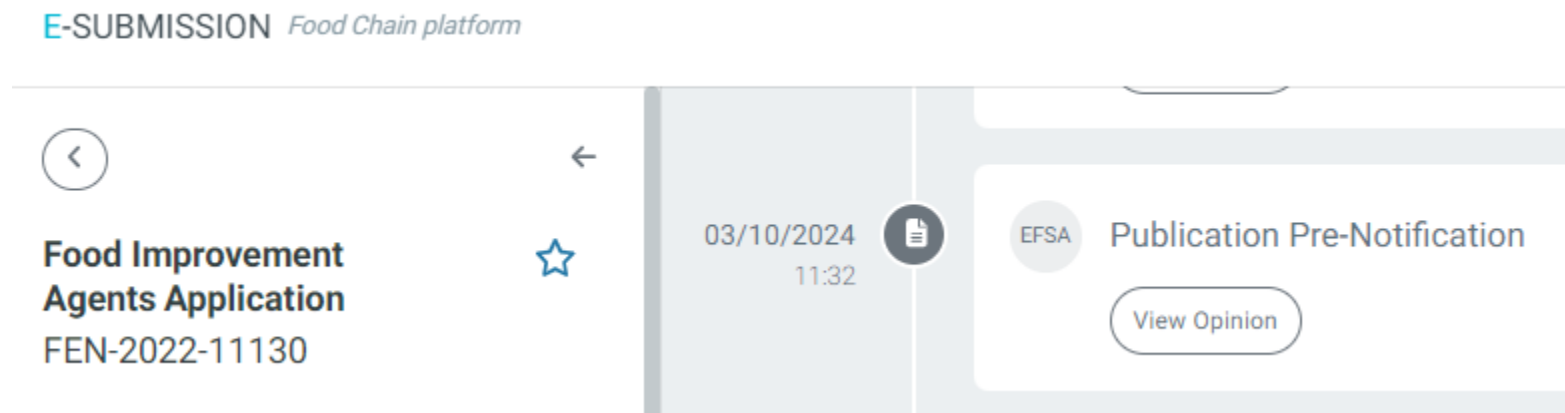
Output Adoption Date: 16 Oct 2024



POST-ADOPTION PHASE – PUBLICATION PRE-NOTIFICATION

EFSA Opinion pre-publication

- What: a **notification informing about the imminent publication**, the opinion is shared under embargo
- When: at least 36 hours before publication
- What: the applicant can inform EFSA on **confidentiality matters** (although no new confidentiality requests can be submitted at this stage), **manifest typographical errors** or other **objective inaccuracies**
- **Deadline for commenting: 24 hours before publication, no extension of deadline**
- **Attachments are not accepted**

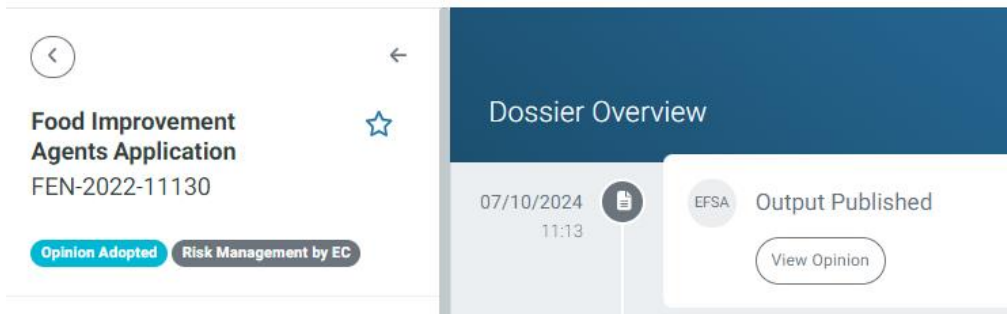


POST-ADOPTION PHASE – NOTIFICATION UPON PUBLICATION

EFSA Opinion published

- What: a **notification** informing about the **publication of the opinion** on the [EFSA Journal](#)

E-SUBMISSION Food Chain platform



Food Improvement Agents Application
FEN-2022-11130

Opinion Adopted Risk Management by EC

Dossier Overview

07/10/2024 11:13

EFSA Output Published

View Opinion

E-SUBMISSION Food Chain platform



Food Improvement Agents Application
FEN-2022-11130

Opinion Adopted Risk Management by EC

EFSA Opinion

Link to publication
File link
7 October 2024 11:13 AM

21 September 2024 1:59 AM
Opinion published by EFSA



POST-ADOPTION PHASE – POST-ADOPTION TELECONFERENCE

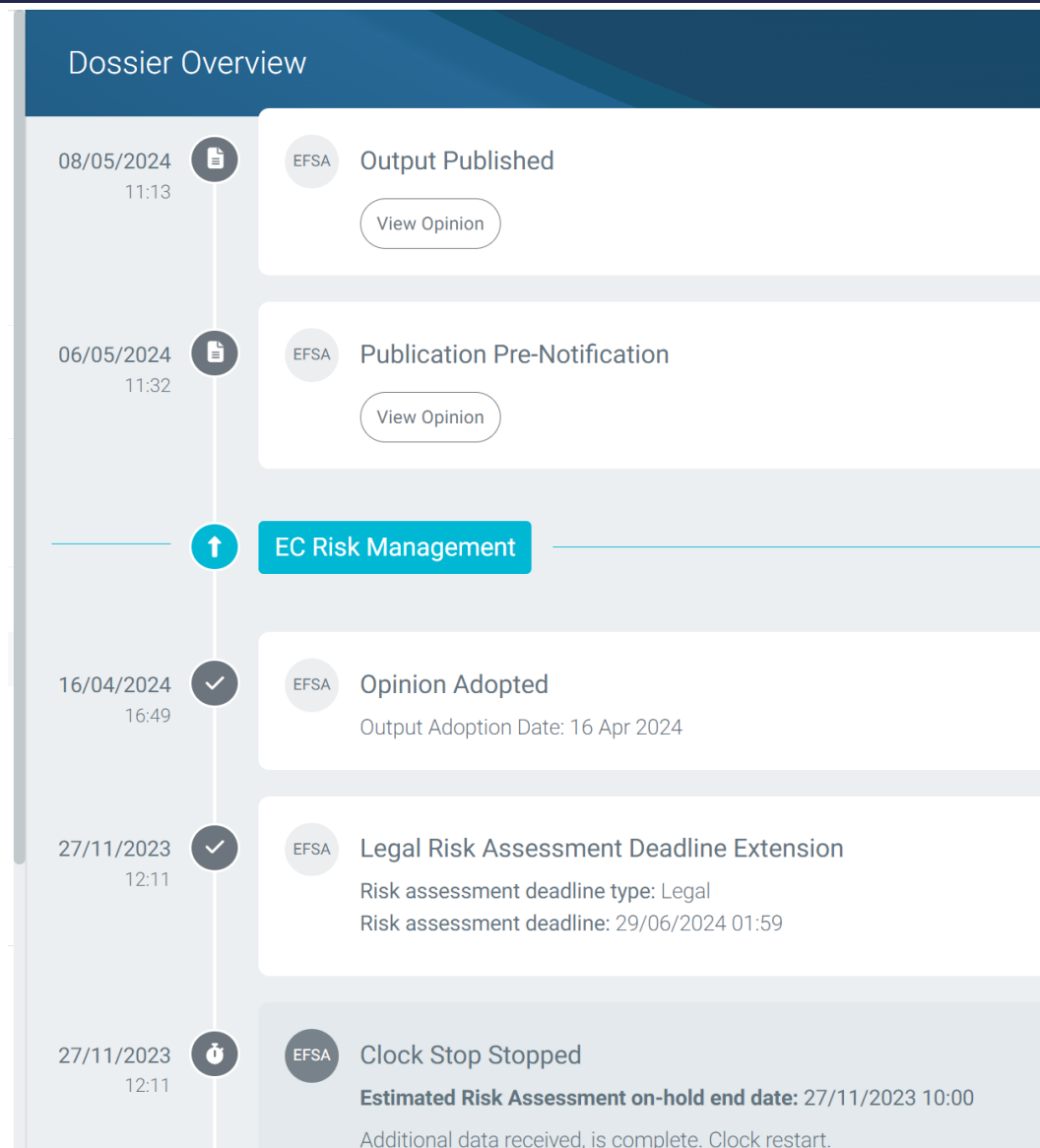
- **What:** A post-adoption teleconference is organised between the applicant and EFSA staff, following the publication of an EFSA scientific output on a regulated product.
- **How to request the service:** e-mail to the Head of the relevant scientific unit
- **Scope:** establishing a dialogue between applicants and EFSA to:
 - i) explain the scientific rationale of the final output from the Panel and/or EFSA;
 - ii) clarify the recommendations of the scientific output (if applicable);
 - iii) clarify the sources of evidence and the factors that influenced the outcome.
- Post-adoption teleconferences are not meant to provide any scientific advice to applicants for future submission.



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

The progress of the dossier can be also followed via [OpenEFSA Portal](#):

FOOD IMPROVEMENT AGENTS

Food Enzymes Authorisation

EFSA-Q-2023-00662 | Status: Published

Last updated: 31/07/2024

Subject

Application for the extension of use of the food enzyme pullulanase from a non-genetically modified *Pullulanibacillus naganensis* strain AE-PL

Substances

Name	CAS
Pullulanase	9075-68-7

Output

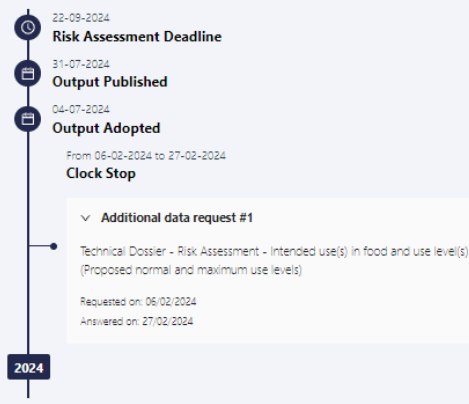
Output Number: ON-8947
Output Type: Scientific Panel or Committee
Publication Date: 31/07/2024
View published version of the output: [See details](#)

Supporting documents

All files

Document Type	Download file
Notification of Studies	PDF (87.5KB)
Request	PDF (232.8KB)
Overarching Mandate	PDF (167.3KB)

Timeline



[See detailed timeline](#)

General Info

Dossier number
[FEN-2023-18432](#)
Applicants
Amano Enzyme Inc.
Mandate number
[M-2021-00094](#)
Question number
EFSA-Q-2023-00662
Question type
Application



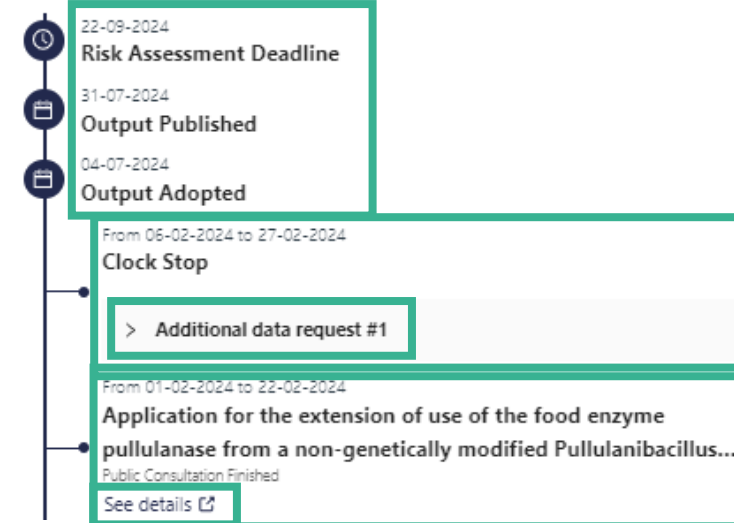
OpenEFSA

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.

Transparent communication

Timeline: EFSA-Q-2023-00662





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**THANK YOU FOR
YOUR ATTENTION**

