AD-HOC MEETING WITH PESTICIDES INDUSTRY ASSOCIATIONS

efsa
EUROPEAN FOOD SAFETY AUTHORITY

AGENDA

15:00 – 15:15
Welcome & Tour de table
EFSA

15:15 – 15:50
Applicants' reliance on the application of current EFSA guidance documents & Discussion
Industry Associations

15:50 – 16:25
EFSA strategy on specific Protection Goals setting & Discussion
Industry Associations

16:25 – 17:00
Overview of support activities to Member States and Applicants in the PESTICIDE process & Discussion
EFSA

HOUSEKEEPING RULES

Please don't record, and let's keep it human – **no AI please!**

EFSA will record for preparation of minutes purposes only

Feel free to **raise your hand** if you would like to take the floor

Questions will be addressed during the meeting,

OVERVIEW OF SUPPORT ACTIVITIES TO MEMBER STATES AND APPLICANTS IN THE PESTICIDE PROCESS

FDP Unit - EFSA

EUROPEAN FOOD SAFETY AUTHORITY

ENGAGEMENT INITIATIVES AVAILABLE TO APPLICANTS and MSs

PRE-SUBMISSION

- GPSA and RPSA
- Support to RMS for pre-submission meetings/advice
- Support on IT tools

RISK ASSESSMENT

- Pre-admissibility teleconferences
- Support to RMS

EFSA EVALUATION

- Clarification teleconferences
- Applicant's hearing

POST-EVALUATION

- Post-adoption teleconferences

AT ANY TIME

- Ask a Question
- Infosession/webinar
- Ad hoc meeting with industry representatives
- PSN subgroup IUCLID
- LinkedIn group
- Info stand and informative sessions in third party events
- Training to industry associations
- Mass mailing, newsletters

SUPPORT DURING THE PRE-SUBMISSION PHASE

General pre-submission advice

- Provided by EFSA together with RMS/co-RMS or EMS, in written or telemeeting.
- Advice on the rules and content of the application. It cannot enter into the study design, endorse or support a hypothesis to be tested.

Renewal pre-submission advice

- Linked to the (mandatory) submission of a list of intended studies (LIS), that the potential applicant is planning to conduct to support the renewal application.
- Provided by EFSA together with RMS/co-RMS following the submission of a LIS and a public consultation.
- Advice in written or telemeeting on the design of the intended studies and the content of the application. It takes into account the outcome of the public consultation.

Pre-submission meetings/advice

- To establish a common understanding between the applicant, RMS and co-RMS regarding a future application.
- Provided by the RMS in writing or during a meeting. The RMS may consult EFSA.

SUPPORT BEFORE THE PEER REVIEW PHASE

Pre-admissibility teleconference

- It is organised by EFSA upon request of the RMS to discuss any topic related to the admissibility check (dossier completeness, NoS information, light confidentiality check) and support them in the processing of the application towards the admissibility.
- Applicants can be also invited to attend.

Advice to RMS during the risk assessment

- Upon request of the RMS, EFSA can support the RMS in specific issues relevant for the assessment

SUPPORT DURING/AFTER THE PEER REVIEW PHASE

Clarification teleconference

- Organised upon request of EFSA or the applicant, with the participation of RMS/co-RMS or EMS
- It can be used to clarify the questions posed during the peer review process, to clarify the rationale of questions and ensure understanding of the request by the applicant

Applicant's technical hearing

- Organised following proposal by the RMS/EMS and in agreement with EFSA
- The applicant is invited to attend a specific agenda point of a Pesticides Peer review meeting:
  - to clarify the additional information provided
  - to clarify any outstanding issue
- The participation of the applicant is limited to the provision of the clarification, the applicant does not participate in any follow up discussion with the experts

Post-adoption teleconference

- Organised upon request of the applicant, with the ad hoc participation of Pesticides Peer review experts/EC
- Used to:
  - explain the scientific rationale of the final output
  - clarify the sources of evidence and the factors that influenced the outcome

ENGAGEMENT INITIATIVES AVAILABLE TO APPLICANTS – AT ANY STAGE

Ask a Question

- To increase understanding on general requirements for submitting applications, procedural steps, status of applications, use of tools (extensive support provided on IUCLID).

Dedicated support to SMEs on the use of IT tools

- Hands-on session provided by EFSA to guide SMEs in the use of the IT tools needed for pre-submission activities and the submission of an application (i.e. Connect.EFSA, Portalino, IUCLID).
- It is recommended to SMEs facing issues when using the tools, it can be requested via the Ask a Question tool.

ADDITIONAL INITIATIVES

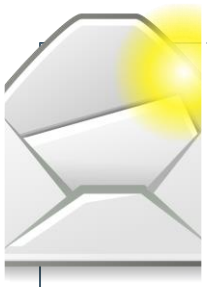
Participation to PSN subgroup IUCLID

LinkedIn group, communication campaigns

Info stands to reach applicants and future applicants to external parties conferences

Training to industry association members

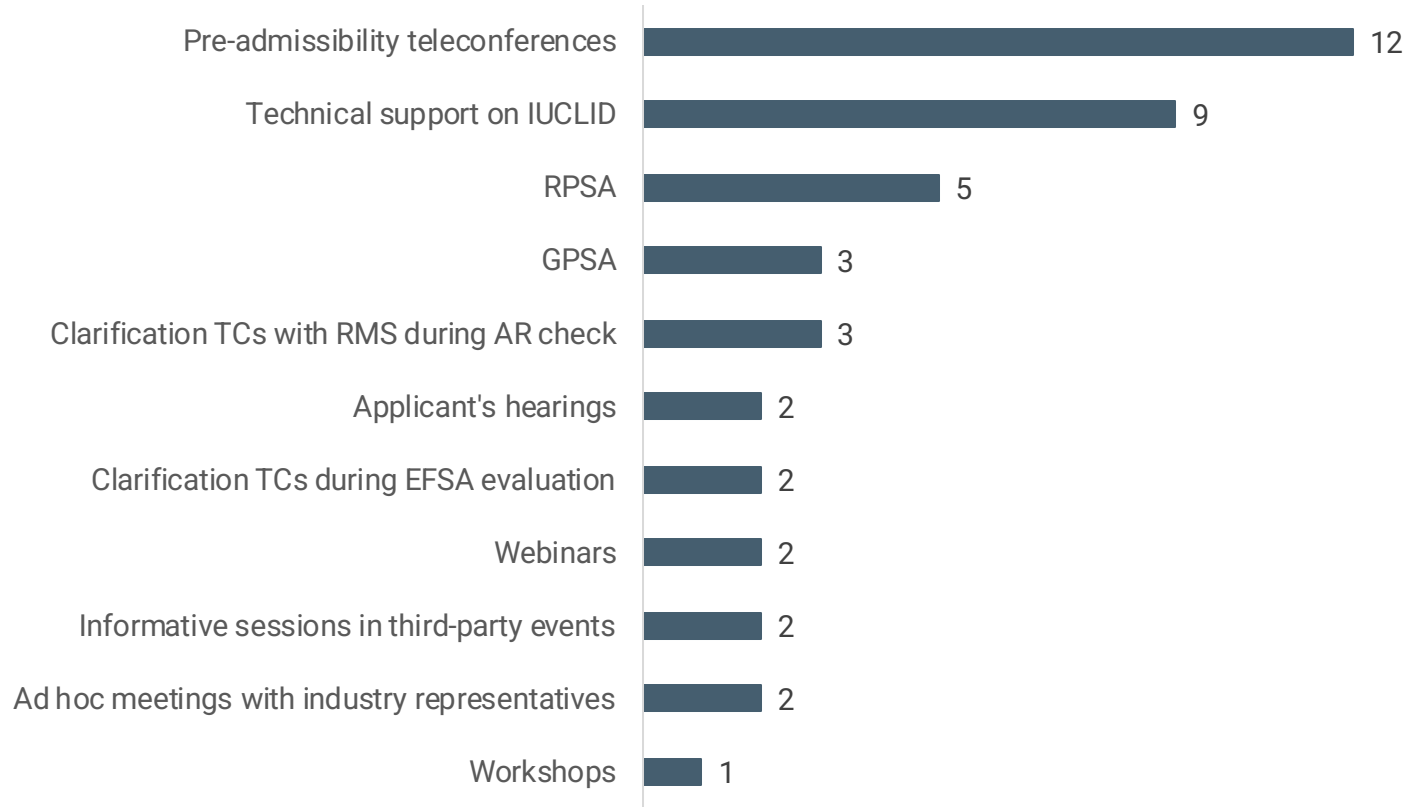
Community on applications (77 submissions from applicants in the area of pesticides)



Mass mailing, Newsletters

SUPPORT INITIATIVES IN 2025 (15/12/2025)

43 INITIATIVES



389 QUERIES received via Ask a Question on pesticide applications
of which 102 on IUCLID

WHAT'S NEXT?

- **Proposal to reinforce pre-submission activities**
  - RMS to organise systematically pre-submission meetings with EFSA for new active substances, and in specific cases for renewals and MRLs, covering also SID
  - For basic substances, applicants to request systematically GPSA

- **Proposal to anticipate certain discussions:**
  - With ad-hoc involvement of applicants to answer specific questions during EFSA-RMS meetings or kick-off peer-review meetings

UPDATE OF ADMINISTRATIVE GUIDANCE

TECHNICAL REPORT

efsa European Food Safety Authority Supporting Publications

APPROVED: 11 February 2021

IMPLEMENTATION DATE: 27 March 2021

LAST UPDATE: 3 June 2024

doi:10.2903/sp.efsa.2021.EN-6464

Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure

European Food Safety Authority (EFSA)

Revision ongoing, an update will be published following consultation with PSN.

Indicatively timeline for republication: Q1 2026

https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2021.EN-6464

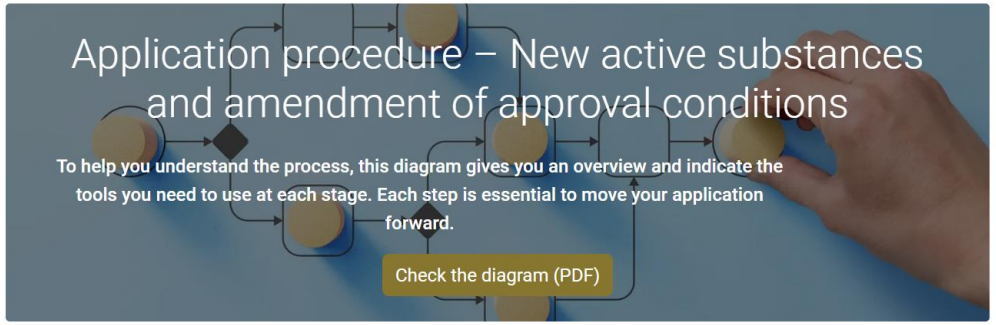
APPLICATIONS WEBPAGE REVAMP: 30 SEPTEMBER 2025

Pesticide active substance and MRL application procedures

Useful overview of the application process

New active substances

For the review of active substances, you have to submit an application dossier through a national contact point. One of the Member States is appointed as "Rapporteur" (RMS) and carries out an initial risk assessment and prepares the Draft Assessment Report (DAR), which is peer reviewed by EFSA together with the Member States.



1. Pre-submission

What do I need to do first? Register in our systems, request advice and notify studies.

2. Submission and admissibility check

Which tool should I use to prepare my dossier?

Are there any tools to help me build my application dossier?

I am ready to submit my application – what do I do next? Use the e-submission system, wait for the RMS/EMS admissibility check.

3. Risk assessment and EFSA's evaluation

What happens after my application has been declared admissible? Risk assessment by RMS/EMS starts

For new active substances and renewals of approval: what happens when the RMS concludes the risk assessment? EFSA's peer review starts

For MRLs: what happens when the EMS concludes the assessment? EFSA's risk assessment starts

4. Post-adoption

What happens following adoption? Publication of EFSA's output & regulatory decision by risk managers.

https://www.efsa.europa.eu/en/applications/pesticides

FAQ: https://connect.efsa.europa.eu/RM/s/faq/topic/0TO1v0000004olSGAY/pesticide-applications

Q&A SESSION

STAY CONNECTED

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