



TOOLS AND OPTIONS FOR ENGAGEMENT WITH APPLICANTS

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Engagement tools in the area of pesticides



Several opportunities for engagement in the [EFSA Catalogue of support initiatives](#)



Overview and information on how to use them



ENGAGEMENT INITIATIVES AVAILABLE TO APPLICANTS

PRE-SUBMISSION PHASE

General pre-submission advice

- Provided by EFSA, together with RMS/co-RMS or EMS upon request of the potential applicant via Connect.EFSA
- Advice on the rules and content of the application. It cannot enter into the study design and hypothesis to be tested

Renewal pre-submission advice

- Provided by EFSA, together with RMS/co-RMS following submission of the list of intended studies by the applicant on Connect.EFSA, and public consultation on the list
- Advice on the list of studies intended to be performed to support the renewal of the a.s., including the study design

Dedicated support to SMEs on the use of IT tools

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

ENGAGEMENT INITIATIVES AVAILABLE TO APPLICANTS

PRE-SUBMISSION PHASE

RMS Pre-submission meetings/advice

- Provided by the RMS in writing or during a meeting
- Scope is to establish a common understanding between the applicant, RMS and co-RMS regarding the dossier to be submitted
- The RMS may consult EFSA. **EFSA involvement is encouraged**, however to make it effective, **RMS needs to provide EFSA with information as complete as possible**

More details in Section 2.2 of the EFSA Administrative guidance on the peer-review of pesticide active substances and MRL applications

EFSA INVOLVEMENT IN PRE-SUBMISSION MEETINGS

Recommendation for the RMS, to ensure effective participation of EFSA

- Inform EFSA about the date of the meeting 3-4 weeks in advance
- Provide the relevant background information (e.g. documents, power point presentations, etc.) to support the discussion, including the specific questions on which advice is sought at least 5 working days before the teleconference;
- Include RMS preliminary consideration on the data submitted by the applicant, e.g.:
 - in case of a position paper sent by the applicant, provide EFSA with RMS evaluation
 - in case of proposal for data waiver from the applicant to a data requirement, provide EFSA with a preliminary assessment of the waiver proposed by the applicant considering the current guidance

ENGAGEMENT INITIATIVES AVAILABLE TO APPLICANTS

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

ENGAGEMENT INITIATIVES AVAILABLE TO APPLICANTS

WHEN THE PEER REVIEW IS CONCLUDED

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)

Infosessions and webinars

- To inform on administrative and scientific issues and to improve the understanding of the application process

Ad hoc meeting with industry representatives

- to exchange views on issues which are unique to a particular scientific area

ADDITIONAL INITIATIVES

Technical group on the Tools related to the application of the Transparency Regulation (TG TOOLS) – Connect.EFSA and Portalino

PSN subgroup IUCLID

LinkedIn group, campaign on IT Tools

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

Mass mailing, Newsletters

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