EFSA update on implementation of TR

M. Tiramani
Head of the Pesticide Peer Review Unit

10 March 2021
Sustainable solutions to protect crops Conference

efsa
European Food Safety Authority

Background

1. Practical Arrangements on EFSA website

2. Regulation (EU) 2019/1381 (Transparency Regulation)

   General pre-submission advice

   Notification of intended studies for renewal and renewal pre-submission advice

   Public consultations

3. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure

PRESUBMISSION ADVICE

General pre-submission advice

- Upon request
- Rules/Content
- No study design
- General
- Expected by small-medium companies

Renewal pre-submission advice

- Systematic and proactive
- Content
- Study design
- Specific
- Follows the public consultation

Non - Committal

Segregation of tasks

Requests for pre-submission advice can still be requested from the RMS outside of the framework of GFL Regulation.

General Pre-submission Advice (G-PSA)

Potential applicant may **request** general pre-submission advice at **any time**

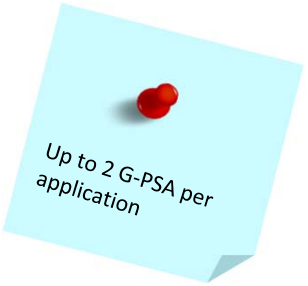
On the **rules** applicable to, and the **content** required for, the application, prior to its submission. Should not address the design of the studies to be submitted

Requests for general pre-submission advice

Submit to EFSA

Cooperation

EFSA in close co-operation with RMS/co-RMS/EMS submits the advice and the summary



**Where is mentioned RMS it should be considered also co-RMS where applicable*
***In case of MRL applications EMS instead of RMS*

General Pre-submission Advice (G-PSA)

Business Operator
Creates and submit
PSA request from PAID

Pre-Submission Advice request

Reject

15 w.d.
APDESK

EFSA has the leading role

Accept

5 w.d. RMS to confirm they will prepare the advice

10 w.d. RMS or EFSA prepares the advice + **5 w.d. for comments**

5 w.d. RMS to confirm that they will prepare the prelim. assessment

10 w.d. RMS or EFSA to prepare preliminary assessment + **5 w.d.** to exchange views/finalise

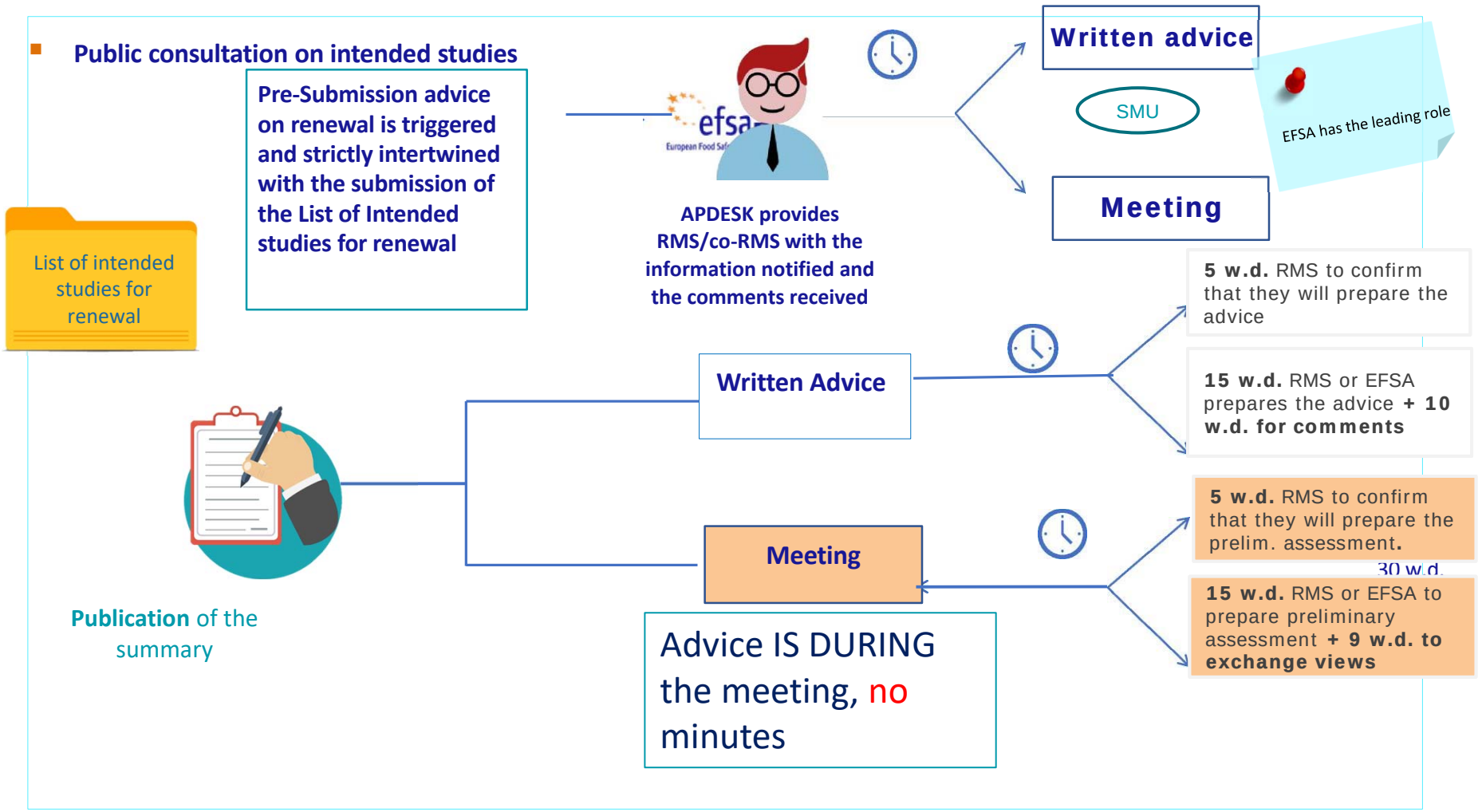
Written

Meeting

Advice IS DURING the meeting, no minutes

Publication of the summary

Renewal Pre-Submission Advice (R-PSA)



Renewal Pre-Submission Advice (R-PSA)

Comments received

Step 1
Written or meeting

Where possible, EFSA shall answer the questions in **writing**

Step 2
Provide the Advice

The written advice shall be provided within **30 working days** as of the closure of the PC;

The meeting shall be organised within **30 working days** as of the date of the closure of the PC

Step 3
Summary

EFSA creates a **summary** proving an overview of the advice which includes how the **comments** were taken into account and sends it to the requester

Public consultation on intended studies for renewal

Submission of intended studies and study design (Article 32c1)

EFSA launches the consultation of third parties on the **intended studies** for renewal

Including on the proposed **design** of the studies

Consultation

The consultation of third parties shall remain open for a period of **three weeks**

Comments

All **comments received** by stakeholders and the public shall be made public by EFSA upon the closure of the public consultation.

Summary of R-PSA

The **results** of the consultation of third parties (i.e. how the comments have been taken into account) shall be inserted in the summary of the renewal pre-submission advice.

EFSA's (main) kinds of PC's

- Draft risk assessment protocol
- Draft scientific output
- DAR/RAR/ED report (PEST)
- List of intended studies for application renewal — New!
- Non-confidential version of a validated application — New!

Notification of studies

Transparency Regulation[1] Article **32b**

1. The Authority shall establish and manage **a database** of **studies commissioned or carried out** by business operators to support an application …

2. For the purposes of paragraph 1, **business operators shall**, without delay, **notify the Authority** …

3. For the purposes of paragraph 1, **laboratories and other testing facilities** located in the Union **shall also**, without delay, **notify the Authority** …

1) Regulation (EC) No 178/2002 as last amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain (aka General Food Law)

Notification of Studies for NAS

Step 1
Pre-submission phase

Sarah

John

The **Business Operator** gets the Pre-Application-ID

Both actors
Notify Studies
(Article 32b)

Database of Study Notifications

Step 2
Submission of application

EFSA validates if submitted studies were notified or justification provided

Step 3
Validation of application

EFSA publishes study notifications
with related studies

Information to be notified - Article 32b

Legend

- Mandatory
- Optional
- Group of elements

Study Title (M) – Free text: title of the study

Study Title (O) – Free text: (English name) title of the study in English language

Study Starting Date (M) – Date: starting date of the study

Study Planned Completion Date (M) – Date: planned completion date of the study

Study scope (G): Section composed of multiple elements.

Notification of Studies for renewals

Step 1
Application renewal

Sarah

The potential applicant gets the Pre-Application-ID for renewal

The potential applicant submits the list of Intended studies and study design (Article 32c1)

Database of Study Notifications

Step 2
Public consultation and R-PSA

EFSA provides advice

Step 3
Notify studies

Sarah

The potential applicant notifies Studies (Article 32b)

List of intended studies for renewal

Transparency Regulation Article **32c**

1. Where the relevant Union law provides that an approval or an authorisation may be renewed, the potential applicant shall **notify the Authority of the studies it intends to perform** for that purpose, including information on how the various studies are to be carried out.

2. Following such notification of studies, the **Authority shall launch a consultation of stakeholders** and the public on the intended studies for renewal, including on the proposed design of studies.

3. Taking into account the received comments which are relevant for the risk assessment of the intended renewal, **the Authority shall provide advice on the content** of the intended renewal application or notification, as well as on the **design of the studies**

Notification of Studies for renewals

Step 1
Application renewal

Sarah

The potential applicant gets the Pre-Application-ID

The potential applicant submit the list intended studies and study design (Article 32c1)

Database of Study Notifications

Step 2
Public consultation and R-PSA

EFSA
Provides advice

Step 3
Notify studies

Sarah

The potential applicant notifies studies (Article 32b)

Intended Studies for renewals - Article 32c1

Legend
- Mandatory
- Optional
- Group of element

Study Title (M) – Free text: title of the study

Study Title (O) – Free text: (English name) title of the study in English language

Former application id (M)– Free text: shall contain the identifier of the application to be renewed (e.g. former EFSA question number)

Study scope (G): Section composed of multiple elements.

Public consultation on intended studies for renewal

Receipt of the list of intended studies for renewal

Step 1
Administrative Check

EFSA launches the consultation of third parties on the **intended studies** for renewal

Including on the proposed **design** of the studies

Within 10 working days from the completion of the administrative check

Step 2
Consultation

The consultation of third parties shall remain open for a period of **three weeks**

Step 3
Comments

All **comments received** by stakeholders and the public shall be made public by EFSA

Step 4
Summary of R-PSA

The **results** of the consultation of third parties shall be inserted in the summary of the renewal pre-submission advice

STAY CONNECTED!

Thank you!

Subscribe to

www.efsa.europa.eu/en/news/newsletters

www.efsa.europa.eu/en/rss

Engage with careers

www.efsa.europa.eu/en/engage/careers

Follow us on Twitter

@efsa_eu

@plants_efsa

@methods_efsa