FEEDBACK FROM PEER REVIEW AND COMPLETENESS CHECK

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OUTLINE

- Update of Planning tables
- Planning peer review meetings
- CLH Obligation
- GAP table
- Data gaps under art.12 of Reg (EC) 396/2005
- Completeness check of DAR/RAR - Leaner process

UPDATE OF PLANNING TABLES

- Updating the planning tables is very important exercise, not only for **planning purposes** but also for the **confidentiality assessment** prioritisation which is needed for the public consultation on the non-confidential version of the dossier (**post-TR**).

active substance	RAR envisaged based on legislation	RAR envisaged based on feedback RMS	Last updated by RMS	RAR submitted to EFSA	Availability/submission of environmental mechanistic effects models in the dossier/RAR (Y/N)	MS planning to comment (put country code)	MS planning to NOT comment (put country code)
1-Naphthylacetic acid (1-NAA)	01/07/2022	31/03/2025	10/06/2024	N	N		
2,5-Dichlorobenzoic acid methylester	03/03/2021	Q1 2024	11/01/2024	13/02/2024	N		
Acetic acid	03/03/2021	01/02/2022	02/12/2021	23/04/2024		NL	
Aclonifen	31/01/2021	01/03/2025	19/07/2024	N			
Aluminium phosphide		01/05/2022	02/12/2021	14/04/2023			

This information will also ensure the **alignment** of the **CLH** and **peer review process** and permit planning and coordination of the upcoming activities by both EFSA and ECHA.

UPDATE OF PLANNING TABLES AND UPLOAD OF DAR/RAR

- It is reminded that RMS should provide EFSA updated information especially in relation to the **expected time of submission of the DAR/RAR** as accurate as possible and to revert back to EFSA even if there are no updates/changes since the last feedback (**email sent to all MSs quarterly**).
- The RMS is also reminded to indicate in the relevant column of the table if there is an intention to prepare a CLH report (indicating the expected time of submission to ECHA and whether the combined AR-CLH template was used)

- When uploading the DAR/RAR to dms, the RMS is also reminded to inform EFSA by sending an email to: FDP@efsa.europa.eu and pesticides.peerreview@efsa.europa.eu in relation to the availability of the AR Volumes and related files.

PEER REVIEW MEETINGS

- Planning peer review meetings **2025** is available *https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/ppr*

Overview of planned
Pesticides Peer Review meetings - 2025 dates

(Planned dates might be subject to change. This table is for information only, for final dates please consult the section "Dates and draft discussion points of upcoming meetings")

Meeting/Section	Start Date	End Date
Mammalian Toxicology and Joint ED	Monday 27 January 2025	Friday 31 January 2025
Environmental Fate and Behaviour	Monday 27 January 2025	Thursday 30 January 2025
Ecotoxicology	Monday 3 February 2025	Friday 7 February 2025
Residues	Tuesday 11 February 2025	Thursday 13 February 2025
Mammalian Toxicology and Joint ED	Monday 10 March 2025	Friday 14 March 2025
Environmental Fate and Behaviour	Monday 10 March 2025	Thursday 13 March 2025
Ecotoxicology	Monday 17 March 2025	Friday 21 March 2025
Residues	Tuesday 25 March 2025	Thursday 27 March 2025
Environmental Fate and Behaviour	Monday 5 May 2025	Thursday 8 May 2025
Mammalian Toxicology and Joint ED	Monday 12 May 2025	Friday 16 May 2025
Ecotoxicology	Monday 19 May 2025	Friday 23 May 2025
Residues	Tuesday 3 June 2025	Thursday 5 June 2025
Mammalian Toxicology and Joint ED	Monday 16 June 2025	Friday 20 June 2025
Environmental Fate and Behaviour	Monday 16 June 2025	Thursday 19 June 2025
Ecotoxicology	Monday 30 June 2025	Friday 4 July 2025
Residues	Wednesday 2 July 2025	Friday 4 July 2025
Mammalian Toxicology and Joint ED	Monday 22 September 2025	Friday 26 September 2025

- RMS, please avoid late changes to the agenda due to unavailability of experts.
- Please consult the planning in advance and inform EFSA of any specific constrains that should be considered.

CLH OBLIGATION

The **obligation** of submitting a **CLH dossier to ECHA,** latest at the time of submission of the **RAR to EFSA**, is laid down in:

- Commission Implementing Regulation (EU) 2020/103 amending Reg 844/2012 applicable to renewal procedures of a.s. for which the
  - ✓ the approval period expires on or after 13.05.2023
  - ✓ the supplementary dossiers was submitted after 24.01.2020
- Commission Implementing Regulation (EU) 2020/1740 on the provisions for the renewal procedure applicable to a.s. for which
  - ✓ the approval period expires on or after 27.03.2024

The rapporteur Member State shall submit a proposal to ECHA to obtain an opinion on a harmonised classification of the active substance at least for the **hazard classes** listed in **Art. 11(9)**.

The RMS should contact ECHA (classification@echa.europa.eu) even in case no changes are proposed to the current CLH and submit the Vol. 1/CLH report and other relevant RAR Volumes in support to the justification why there is no CLH proposal.

GAP TABLE

The GAP describes the intended or registered safe use of plant protection products and should be presented accurately in the DAR/RAR to ensure an appropriate risk assessment is undertaken.

- The RMS is reminded that **lower risk GAPs** (lower application rate or lower number of applications) should be considered in a more systematic way during the preparation of the initial DAR/RAR.

  This will ensure the information is available at the beginning of the peer-review process and can be commented by all parties, instead of being submitted only after the clock stop.

GAP TABLE

- The GAP table submitted in Vol.1 and LoEP should be **in line** and presented in the **new format** (should not be repeated in other parts of the DAR/RAR).
- The GAP table submitted in the DAR/RAR should be **consistent with the GAP in the dossier**
  - ✓ Document D1 for pre-TR dossiers
  - ✓ IUCLID GAP from report generator for post-TR dossiers.
- Changing the GAP is not permitted during the ongoing peer-review.

During the completeness check, the RMS is asked to confirm that the GAP in the DAR/RAR is the **latest version** and was **agreed with the Applicant**.

GAP format as included in the combined template: https://food.ec.europa.eu/document/download/5a067575-40fa-4fb3-93f1-640d0a8a6984_en?filename=pesticides_ppp_app-proc_guide_doss_12592-2012.zip

ASSESSMENT OF DATA GAPS IDENTIFIED UNDER ART.12 OF REGULATION (EC) 396/2005

For **data gaps** that were identified by EFSA in the framework of the **MRL review** according to Art. 12 of Regulation (EC) No 396/2005 and confirmed by the EC, the RMS is reminded to inform EFSA pesticides.mrl@efsa.europa.eu once the data requested have been submitted by the authorization holders and to indicate under which regulatory framework these are intended to be assessed.

- In case the data gaps will be assessed under the procedure set out in Chapter II of Regulation (EC) No 396/2005 (hereinafter "**Article 6 application**"), the RMS/EMS should prepare an **Evaluation Report** to assess those data.

- In case the data gaps will be assessed within the **Renewal procedure**, the RMS should clearly explain in **Volume 1 of the RAR** which data gaps were assessed within the renewal procedure and the respective **Vol. 3 CA/CP** where the studies/information are evaluated.

COMPLETENESS CHECK OF DAR/RAR : LEANER PROCESS

- In order to speed up the Completeness check phase and facilitate the revision work by the RMS, we are implementing a new system for the CC.
- Instead of listing in an email all deficiencies found during CC in the various DAR/RAR volumes, we include comments or edit (in track changes) the word version of the DAR/RAR submitted by the RMSs.
- When undertaking the revision, the RMS could then accept the track changes and/or perform the relevant modifications in the text in line with what requested in the comments.
- The pdf versions of the modified/edited volumes should be created by the RMS on the final agreed word version.

Give us your feedback on the proposed approach and issues encountered.

Do you have any suggestion to improve the communication during completeness check?

DMS EDIT FUNCTION AND SUPPORT

- In case you experience issues with the **open/edit function** in **DMS**, we recommend you install in your computer

✓ **Content Server Web Browser Extension** and

✓ **Open text Office Editor Application**

- After the installation, documents on the EFSA DMS should be edited using the **Chrome browser** via the edit button.

- Should you still experience issues, please contact directly servicedesk@efsa.europa.eu and keep FDP@efsa.europa.eu in copy.

EFSA’S SUPPORT TO MEMBER STATES

EFSA can participate in the pre-submission meetings upon requests of the RMS

EFSA can support the RMS on IUCLID issue and during the admissibility process

RMS are reminded to use report generator during admissibility and risk assessment

EFSA is available to further support the RMS during CC and ad-hoc teleconferences can be organized

EFSA can support the RMS on complex issues

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