

11th meeting of the PSN IUCLID sub-group
21 November 2024

CONFIDENTIALITY ASSESSMENT ON THE DOSSIER THROUGHOUT THE RISK ASSESSMENT LIFE-CYCLE

LEGAL AFFAIRS UNIT



Confidentiality Assessment on the dossier throughout the RA Life-cycle - OVERVIEW

The below is applicable to approvals of new active substances (NAS)/amendments to approval conditions (AMEND), Renewals & MRLs:

Following admissibility

1) confidentiality assessment on admissible* dossier

Upon conclusion of confidentiality assessment on admissible dossier:

- implementation by Applicant (if needed),
- publication of filtered dossier post-confidentiality, and
- launch of the public consultation on filtered dossier.

Following adoption of the EFSA scientific output

2) confidentiality assessment on final dossier**

Upon conclusion of confidentiality assessment on final dossier, implementation by Applicant (if needed) & publication of filtered dossier post-confidentiality.

*by "*admissible dossier*" we mean the version of the dossier declared admissible (subject to administrative changes, if any, resulting from EFSA light check)

**by "*final dossier*" we mean the version of the dossier containing all additional data requested by MS/EFSA in connection with the risk assessment



CONFIDENTIALITY ASSESSMENT ON ADMISSIBLE DOSSIER

▪ Renewals/MRLs

- A. **EFSA** assesses confidentiality requests (CRs) on admissible dossier **upon declaration of admissibility** – OVERALL legal DL: *10 calendar weeks from admissibility*
- B. If CR(s) is/are rejected, **EFSA** requests Applicant to implement the decision within reasonable time-frame by **re-submitting the dossier in IUCLID** modified in accordance with the decision, and forwards the decision to EC, EFSA and other MS – OVERALL legal DL: *at the latest 1 month from notification of confidentiality decision*

▪ NAS/AMEND

- A. **RMS** assesses CRs on admissible dossier **upon declaration of admissibility** – OVERALL legal DL: *10 calendar weeks from admissibility*
 - 1. **RMS** consults EFSA on its draft confidentiality decision – legal DL for sub-step: *4 calendar weeks from admissibility*
 - 2. **EFSA** comments RMS' draft confidentiality decision – legal DL for sub-step: *10 working days from the receipt of RMS draft decision*
 - 3. **RMS** finalises confidentiality assessment – legal DL for sub-step: *4 calendar weeks from receipt of EFSA comments*
 - This step includes sharing draft confidentiality decision for comments with Applicant if one or more CRs are to be rejected
 - **Applicant** can comment RMS' draft confidentiality decision – legal DL for sub-step: *1 calendar week from notification of draft decision to Applicant*
- B. If CR(s) is/are rejected, **RMS** requests Applicant to implement the decision within reasonable time-frame by **re-submitting the dossier in IUCLID** modified in accordance with the decision, and forwards the decision to EC, EFSA and other MS – OVERALL legal DL: *at the latest 1 month from notification of confidentiality decision*



CONFIDENTIALITY ASSESSMENT ON FINAL DOSSIER

▪ Renewals/MRLs

- A. **EFSA** assesses confidentiality requests (CRs) on final dossier **upon notification of adoption of EFSA OUTPUT**– OVERALL timeline: *10 calendar weeks from notification of output*
- B. If CR(s) is/are rejected, **EFSA** requests Applicant to implement the decision within reasonable time-frame by **re-submitting the dossier in IUCLID** modified in accordance with the decision, and forwards the decision to EC, EFSA and other MS - OVERALL timeline: *at the latest 1 month from notification of confidentiality decision*

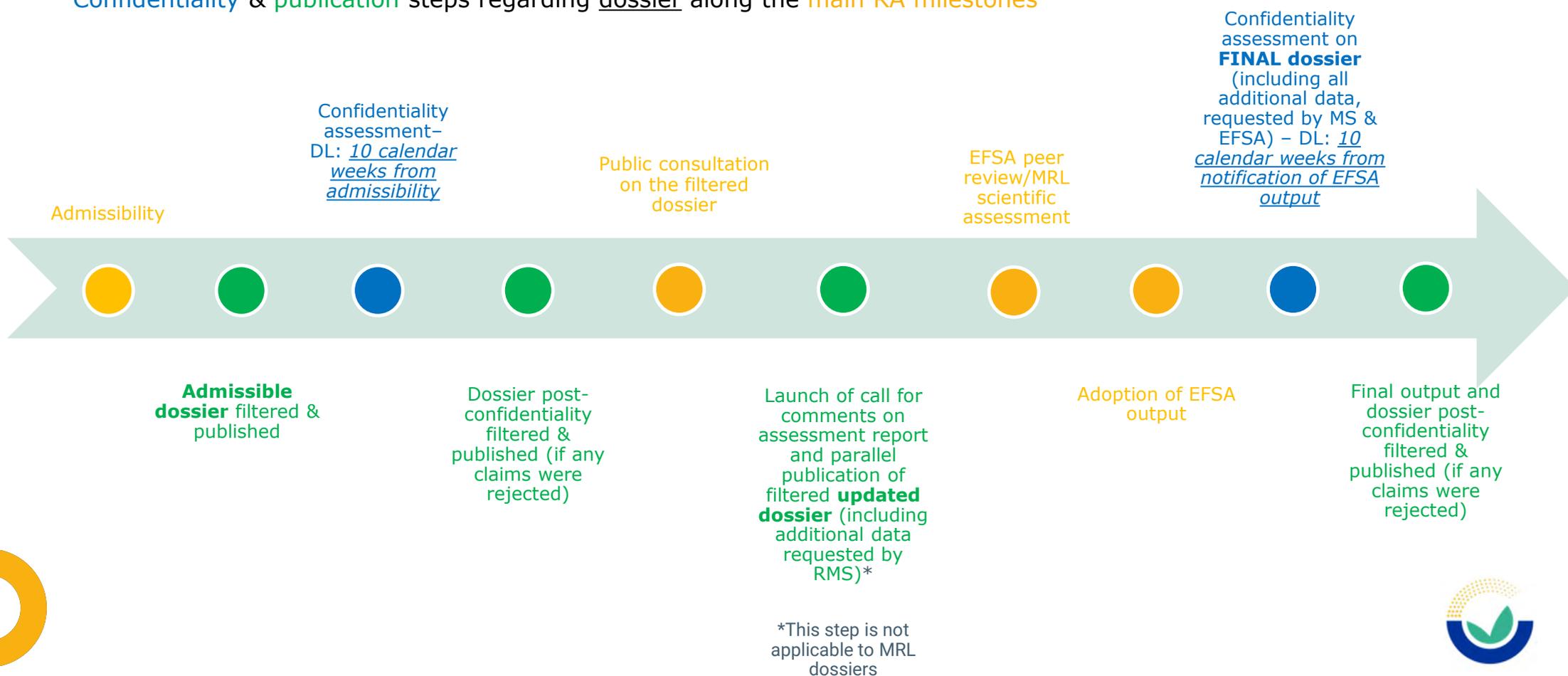
▪ NAS/AMEND (Article 7 of Practical Arrangements concerning confidentiality in accordance with Article 7(3) and 16 of Regulation (EC) No 1107/2009 to be applied *mutatis mutandis*)

- A. **RMS** assesses CRs on final dossier **upon notification of adoption of EFSA OUTPUT** – OVERALL timeline: *10 calendar weeks from notification of output*
 - 1. **RMS** consults EFSA on its draft confidentiality decision – DL for sub-step: *4 calendar weeks from notification*
 - 2. **EFSA** comments RMS' draft confidentiality decision – DL for sub-step: *10 working days from the receipt of RMS draft decision*
 - 3. **RMS** finalises confidentiality assessment – DL for sub-step: *4 calendar weeks from receipt of EFSA comments*
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- B. If CR(s) is/are rejected, **RMS** requests Applicant to implement the decision within reasonable time-frame by **re-submitting the dossier in IUCLID** modified in accordance with the decision, and forwards the decision to EC, EFSA and other MS - OVERALL timeline: *at the latest 1 month from notification of confidentiality decision*



Confidentiality Assessment/Proactive Dissemination related to the dossier throughout the RA Life-Cycle - RECAP

Confidentiality & publication steps regarding dossier along the **main RA milestones**



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