

15th meeting of the PSN IUCLID sub-group

15 April 2026

SUBMISSION AND PROCESSING OF CONFIDENTIALITY REQUESTS ON ASSESSMENT REPORTS (DAR AND RAR)

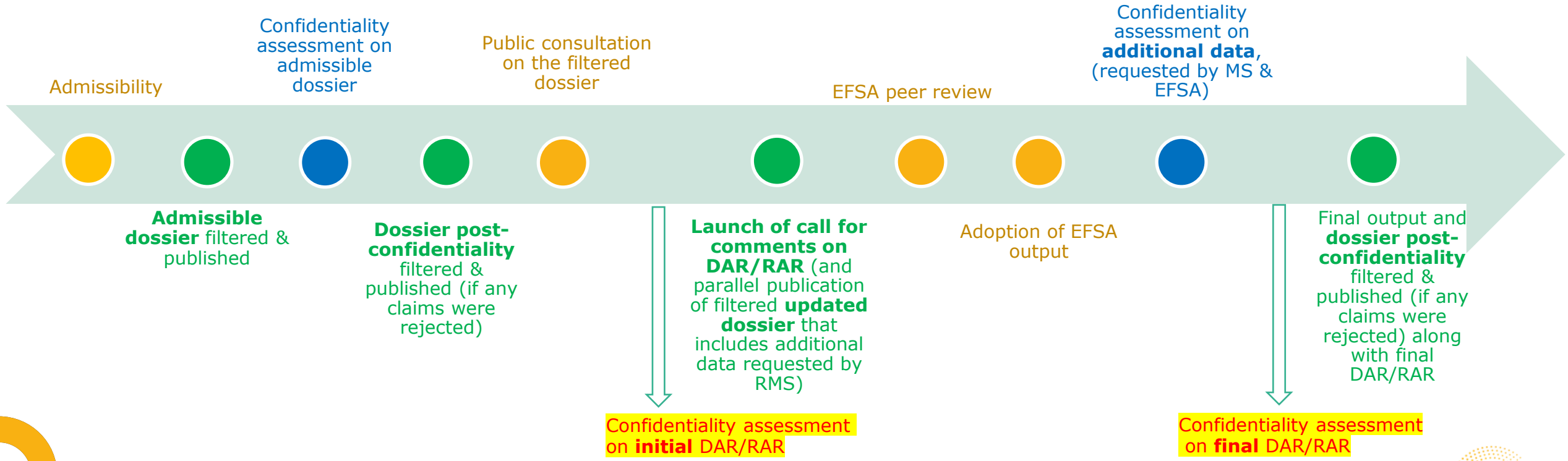
LEGAL AFFAIRS UNIT

Team Confidentiality Pesticides

EUROPEAN FOOD SAFETY AUTHORITY

DAR/RAR : Timelines

Confidentiality assessment throughout the Risk Assessment life cycle:
when and where do the DAR/RAR occur?



SUBMISSION AND ASSESSMENT OF CONFIDENTIALITY REQUESTS ON INITIAL DAR/RAR

- EFSA transmits the **initial DAR/RAR**; applicants submit **confidentiality requests** together with **confidential (marked)** and **non-confidential (sanitised)** versions
- Confidentiality requests are submitted via **Portalino** within **two weeks** of receiving notification from EFSA, for the full set of DAR/RAR volumes (including Vol. 4)
- Confidentiality requests must be **linked to the DAR/RAR files,** and Portalino supports the submission of verifiable justifications
- **EFSA Legal Unit** assesses all requests and issues a confidentiality decision in accordance with **Articles 39–39e of the General Food Law ("GFL")**

KEY CONSIDERATIONS

- The confidentiality assessment of the **initial DAR/RAR** is **independent** of that of the **valid IUCLID dossier** of origin
- However, when submitting confidentiality requests in the initial DAR/RAR, applicants should consider the outcome of the confidentiality decision for the same elements in the valid IUCLID dossier of origin
- Once the confidentiality assessment has been finalised, the **sanitised DAR/RAR** will be published **on OpenEFSA** for a **60-day public consultation**
- An updated IUCLID dossier may be republished alongside the initial DAR/RAR, but no confidentiality assessment is conducted on the additional data in IUCLID at this stage

FINAL DAR/RAR DISPATCH:TIMELINES AND CONFIDENTIALITY

- EFSA shares **the final DAR/RAR** with the applicant
- Applicants have **two weeks to submit confidentiality requests** for the **final DAR/RAR** via **Portalino** along with confidential (marked) and non-confidential (sanitised) versions
- When submitting these requests, applicants need to consider the outcome of the confidentiality decision for the same elements in the initial DAR/RAR and in the IUCLID dossier
- **EFSA Legal Unit issues a confidentiality decision on final DAR/RAR**
- Once the confidentiality assessment has been finalised, **the sanitised DAR/RAR is published as a supporting document for the output**

CONCLUSION

Importance of Compliance

Adhering to DAR/RAR dispatch and confidentiality assessment safeguards regulatory compliance and ensures transparent processes

Key Process Stages

Processes include the transmission of relevant documentation, the submission and assessment of confidentiality requests, and public consultation

For reference