12th meeting of the PSN IUCLID sub-group
11-12 March 2025

RMS' CONFIDENTIALITY ASSESSMENT

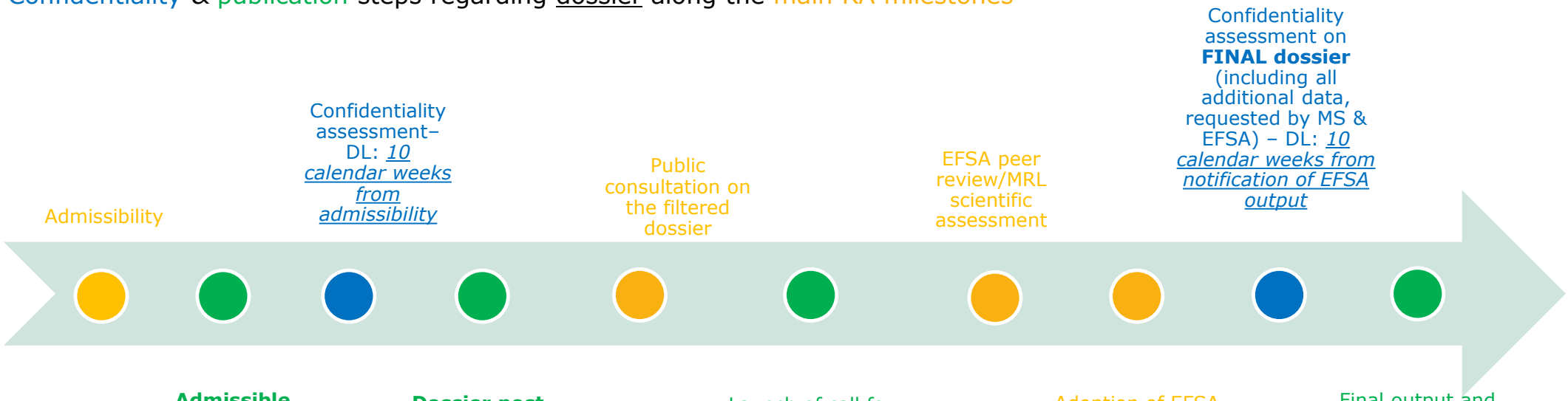
APPROVALS OF NEW ACTIVE SUBSTANCES (NAS) & AMENDMENTS TO APPROVAL CONDITIONS (AMEND)

LEGAL AFFAIRS UNIT

efsa
EUROPEAN FOOD SAFETY AUTHORITY

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

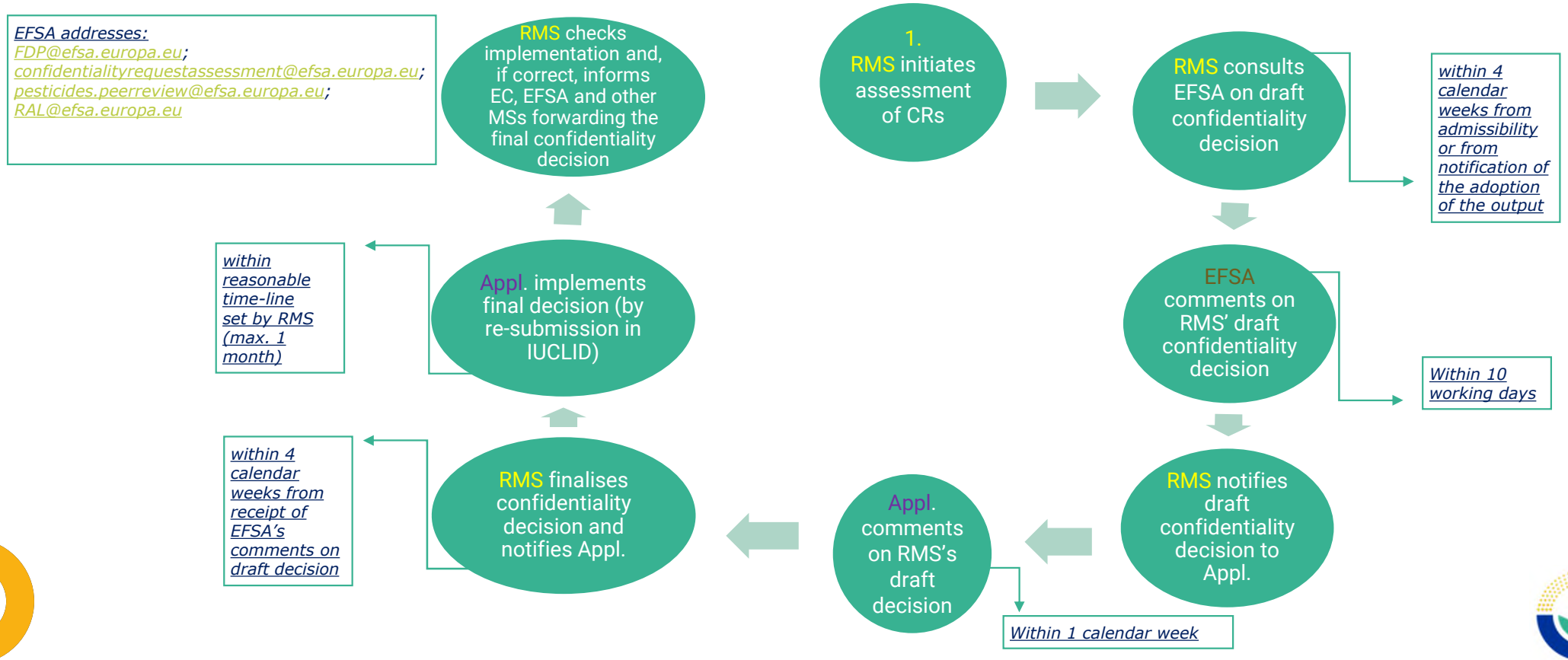
Confidentiality & publication steps regarding dossier along the main RA milestones



*This step is not applicable to MRL dossiers

Confidentiality Assessment for NAS/AMEND - OVERVIEW

Steps and timelines of confidentiality assessment **on admissible dossier** upon declaration of admissibility (first confidentiality assessment) AND **on FINAL dossier** upon notification of adoption of EFSA OUTPUT (second confidentiality assessment)



Article 7 of Practical Arrangements concerning confidentiality in accordance with Article 7(3) and 16 of Regulation (EC) No 1107/2009

RMS' CFD ASSESSMENT AND CONSULTATION OF EFSA ON DRAFT DECISION: scope of the assessment and scope/limit of the consultation

- The **RMS** confidentiality decision - similarly to that of EFSA for renewals/MRLs - should include a **thorough and specific reasoning** explaining the outcome for **each confidentiality claim**.

***NB**: as interlinked with the cfd. assessment on the NAS/AMEND dossier, also claims on the related NoS extract need to be assessed by RMS*

- In the context of the EFSA consultation on the RMS draft confidentiality decision, EFSA's role is to provide **punctual feedback** with a view to ensuring **consistency** between EFSA and RMS confidentiality assessments; not to review all confidentiality requests from scratch.

Tips to facilitate EFSA's consultation:

- before sharing the draft confidentiality decision with EFSA for consultation, the **RMS should carry out a diligent assessment**; if there are any procedural/technical issues preventing the RMS from doing so (e.g., lack of/poor identification of the information claimed confidential; absence of justification/incomplete justification; absence of specific legal ground (e.g., "*Article 63(2)(c) of Regulation (EC) No 1107/2009 – results of production batches*") this should be **flagged to the applicant and addressed before sharing the draft confidentiality decision with EFSA**
- the draft decision should be shared with the Confidentiality Pesticides team (confidentialityrequestassessment@efsa.europa.eu) in an **editable format** (i.e. Word/rtf)
- the draft decision should contain **RMS' preliminary assessment in writing**
- the preliminary assessment should contain **thorough and specific reasoning explaining the outcome for each confidentiality claim**

RMS' CONFIDENTIALITY ASSESSMENT: HOW TO ASSESS CONFIDENTIALITY REQUESTS/CLAIMS (CRs)

RECOMMENDATIONS

- ✓ To extract the "***list of confidentiality claims***" from the IUCLID Uploaded reports via the "Report Generator" function
- ✓ To contact EFSA through the Ask a question function on the official EFSA website in case of technical issues/questions
- ✓ To request clarification from the Applicant when information provided by them does not allow the RMS to draft a confidentiality decision (i.e. missing attachment(s), missing justification(s) or justifications with missing legal ground/imprecise identification of the information claimed confidential etc.)

ATTACHMENTS

To verify whether each attachment*, for which the Applicant submitted a CR, is uploaded in its:

- ➢ **confidential** version **(containing earmarking)**
- ➢ **non-confidential (sanitised)** version for publication

* Except for:
- attachments included in IUCLID dossier for consideration by RMS when drawing up the DAR/RAR, and
- attachment containing confidentiality request justifications included in IUCLID dossier in view of the character limitation in the confidentiality request justification box.

JUSTIFICATIONS

To check that each single justification contains:

- ➢ **a clear identification** of each item claimed confidential (must match the earmarking in the confidential v. and the masked items in the sanitised v.)
- ➢ the **correct legal basis** for each distinct item claimed confidential i.e.:
  - CBI among one of the categories listed in Art. 63(2) from (b) to (d) of PPP Reg. and 39(2) from (a) to (d) of the GFL
  - Personal data under Art. 39e(2) and (3) of General Food Law (see the non-exhaustive list on electronic page 40 of EFSA User Guide)
- ➢ **for CBI**, the rationale for the award of confidential status (declaration of compliance with **cumulative substantive requirements** as set in the Practical Arrangements concerning Transparency and Confidentiality, see electronic page 35 of EFSA User Guide on Confidentiality)

RMS' CONFIDENTIALITY ASSESSMENT: DRAFT DECISION

PRELIMINARY ASSESSMENT IN WRITING, MILESTONES:

- The award of confidential status is an exception to the principle of transparency
- The assessment of each individual confidentiality request against the previously mentioned criteria may therefore lead to the following **conclusions**:

  a) the **acceptance** of the request;

  b) the **rejection** of the request either in full or in part.

Example for partial rejection: the confidentiality can be accepted for personal data as compliant with Article 39e of Regulation (EC) No 178/2002 but rejected for (some of) the items that the Applicant identified as confidential business information (because they are publicly available, or the legal ground is not correct, or the attachments are fully masked following a generic legal basis etc)

- As a **consequence** of acceptance/rejection, RMS requires the Applicant:

- [for attachments]

a) **to keep** the elements claimed confidential **sanitised**/**masked**/redacted in the non-conf. version for publication (**accepted** elements)

b) **to unmask** the elements for which the confidential status cannot be granted in the non-conf. version for publication (**rejected** elements)

- [for IUCLID fields]

a) **to keep** the confidentiality **flag** in case of **acceptance**

b) **to remove** the confidentiality **flag** in case of **rejection**

- The i. **reasoning**/considerations, ii. **conclusions** (acceptance/rejection) and ii. the related **consequences** (i.e. **actions**) for Applicants in terms of implementation **MUST be put in writing in the draft decision for each confidentiality request**

SUPPORT FROM CONFIDENTIALITY PESTICIDES TEAM

- Write to confidentialityrequestassessment@efsa.europa.eu for further guidance on specific topics/issues related to confidentiality
- *Ad hoc* clarification conferences on confidentiality possible on a need-basis
- Updates of EFSA User Guide on Confidentiality to be published soon (Q1 2025), including *inter alia* further guidance on CBI
- Colleagues from Confidentiality Pesticides team to systematically join teleconferences with MS organised by FDP if relevant

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