7th meeting of the PSN IUCLID sub-group
19-20 June 2023

FEEDBACK FROM EFSA ON POST-ADMISSIBILITY STEPS

Silvia Mazzega
Federica Bruno

EUROPEAN FOOD SAFETY AUTHORITY

POST – ADMISSIBILITY STEPS

- PUBLICATION of the non-confidential version of the dossiers in the 'public' IUCLID
- CONFIDENTIALITY REQUESTS ASSESSMENT: assessment of the confidentiality request presented by the applicant in the dossier. If confidentiality requests are rejected on the admissible dossier, an updated non-confidential version is published upon implementation of the confidentiality decision
- PUBLIC CONSULTATION on the non-confidential version of the dossier
- RAR/DAR PREPARATION with assessment of the comments received on the dossier

CONFIDENTIALITY REQUESTS ASSESSMENT – NAS VS RENEWALS

Application for approval of a **new active substance** or **amendment** to the conditions of approval of an active substance

→ Assessed by the **RMS**; subject to a mandatory consultation of EFSA confidentialityrequestassessment@efsa.europa.eu

The RMS must communicate the date and outcome of their confidentiality request assessment and provide a copy of the confidentiality decision document to the EC/MSs and EFSA.

RMS must provide EFSA with the UUID of the IUCLID dossier which will be subject to the public consultation.

Applications for **renewal** of the approval of an active substance

→ Assessed by **EFSA**

In case one or more requests for confidentiality are rejected, the applicant is responsible to implement the confidentiality decision by updating the information in IUCLID.

CONFIDENTIALITY REQUESTS ASSESSMENT

- Practical Arrangements (PAs) concerning confidentiality in accordance with Article 7(3) and 16 of Regulation (EC) No 107/2009 (Article 7(6)) **requires RMS to consult EFSA** (confidentialityrequestassessment@efsa.europa.eu) on their draft confidentiality decision regarding confidentiality requests on NAS dossier)

- Mandatory consultation of EFSA applies to each and every RMS confidentiality assessment for NAS dossiers

- Objective: ensuring **consistency** between EFSA's & RMS' confidentiality assessments on identical or similar items included in pesticide dossiers

PUBLIC CONSULTATION

The consultation is launched on EFSA's website:
https://www.efsa.europa.eu/en/calls/consultations

- it lasts **3 calendar weeks** in case of applications for **new active substances** and **amendment** of approval conditions

- the one on **renewal** applications lasts **60 days**.

Comments received from third parties will be made public by EFSA upon the closure of the consultation of third parties and will be brought to the attention of the RMS.

Relevant comments should be considered by the RMS during the risk assessment and preparation of the assessment report/evaluation report. The assessment report (DAR/RAR) should clearly report in an annex how the comments received have been taken into account.

COMMENTS RECEIVED ON THE DOSSIER

- A template will soon made available on EFSA Knowledge Junction. This is the model table to be included as an Appendix to Vol.1:

Comment	Comment considered relevant	How the comment was addressed by the RMS	Cross-reference to the RAR volume and section
Text of Comment 1	Y/N	e.g. the literature study reported in the comment has been requested to the applicant and has been evaluated in the dedicated section of the DAR/RAR	e.g. Vol 3 CA B6, Section XX.XX
Text of Comment 2	Y/N	…	….

- In relation to the DAR/RAR template, no update is foreseen

SUBMISSION OF THE ASSESSMENT REPORT

The RMS must make available to EFSA the **draft assessment report** at the latest:

- 12 months after admissibility of the dossier in case of application for approval or amendment of approval conditions
- 13 months after submission of the application for renewal.

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