IMPROVEMENT IN PEER REVIEW

FEEDBACK FROM PEER REVIEW AND COMPLETENESS CHECK, UPDATE OF THE Q&A ON NOS

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OUTLINE

- Update of Planning tables
- Opportunities for improvement of the peer review process
- Soil metabolites leaching the GW
- Feedback from Completeness check of DAR/RAR
- Notification of studies (NOS): update on Q&A

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**).
- It is reminded that RMS should provide EFSA updated information 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).
- RMS should indicate in the relevant columns of the table if intends to prepare a **CLH report** (when there is planned to submit to ECHA; if separate CLH report or using the **combined DAR-CLH template**) for alignment with the peer review to permit planning and **coordination** of the upcoming activities by both EFSA and ECHA.
- **NAS DAR and AIR III/IV/V RAR submission tables are updated and available on EFSA DMS (for MS use)**

OPPORTUNITIES FOR IMPROVEMENT

- Issues with submitted revised assessment:

  ⇒ Standard quality

  ⇒ Timely submission

  ⇒ Transparent inclusion of all evidence submitted in support of the (renewal) of the approval (including e.g. the outcome of the peer review meetings, studies submitted by the applicant etc).

- This would
  - avoid unnecessary delays
  - follow up mandates

- Issues with incomplete data sets (see next slides)

INCOMPLETE DATA SETS IN THE DOSSIER/INITIAL DAR/RAR / 1

- **Incomplete data set may be particularly important in case ED data set is considered incomplete by the RMS** in the initial RAR **for the substances where the 2nd ED clock stop is no longer applicable.**
- In some cases, the RMS concludes in the initial RAR that additional testing/studies are needed. As a consequence, the **ED data set is considered incomplete, compromising the possibility to perform a comprehensive evaluation of the ED potential to allow an efficient peer review and eventually leading to inconclusive outcomes.**
- **Situation is not new and not specific to ED : issue of incomplete data set applies to all endpoints (not only ED) and normally the same approach should be followed for all endpoints**
  - the ED clock stop was only a **temporary measure in place**, and subsequently in principle the **ED endpoint should be treated in the same way as the other endpoints**
  - with the cease of the 2nd ED clock stop, there are no other specific rules in place in the legislation for the ED endpoint, so a different approach from other endpoints should be justified
- **Overall, it is the APPL responsibility to address the data requirements as set by the legislation.**
  - In case of no data were submitted => there could be also cases when APPL may wish to consider a **potential ED waiver** which might not be agreed by RMS in the DAR/RAR.
  - In certain cases, it may be the **APPL choice** and **business strategy not to invest in** performing the studies despite the known lack of data (or purely based on RMS view)

INCOMPLETE DATA SETS IN THE DOSSIER/INITIAL DAR/RAR / 2

⇒ Possibilities before dossier/DAR/RAR submission:

- **APPL can benefit of pre-submission meetings with the RMS (before submission of the dossier)** and for specific/complex cases **RMS can also request EFSA participation** in the meeting (this forum can be appropriate to discuss the need of additional data but **still a pre-assessment of data is not aimed since that is the subject of the peer review**)
- **RMS could liaise with the APPL prior to the submission of the initial DAR/RAR in order to provide a complete data set for the scientific check stage**:
    - the RMS has the opportunity to request additional information to the APPL, however only 6 months are allocated to the applicant to submit supplementary data (for NAS), while for renewals there is no possibility to extend the 13 months allocated for drafting the RAR) => for missing longer term studies may not prove to be workable.
- **RMS may consider a dossier inadmissible** if quality is too low. For **IUCLID dossiers** validation rules are used so if RMS spot recurrent parts of dossier incomplete, these should be shared with EFSA so we can explore possibility of introducing new validation rules for dossiers at entry.
- It is reiterated that **EFSA does not assess the dossier but peer review the RMS's assessment of DAR/**does not have the legal ground to reject a DAR/RAR due to incomplete data set whilst the dossier has been considered admissible already by the RMS, therefore, rejection should be considered rather by the RMS at dossier level.
- In a nutshell, **incomplete data set should be addressed at RMS level** before submission of the DAR/RAR rather than leaving inconclusive assessment to be escalated to the peer review and finally to the decision making phase.

INCOMPLETE DATA SETS IN THE DOSSIER/INITIAL DAR/RAR /3

⇒ Possibilities during the peer review process:

- **EFSA** follows the standard practice applied for any other endpoint, i.e. to set **data requirement** and ask for **additional information** during the 1st clock stop.
- EFSA cannot reject the DAR/RAR at CC phase due to incomplete data supplied by APPL. The quality of DAR/RAR entering the peer review may be compromised if the quality of the dossier is low.
- Ideally, **RMS** should come back to EFSA at an earlier stage, still **before the submission of the RAR**, for any **advice on the ED assessment**, in order to avoid confronting issues/missing data set after the RAR has been submitted when finding a remedy is already too late.

⇒ RMS should provide **complete DAR/RAR** to allow a comprehensive assessment and an efficient peer review to be carried out, avoiding inconclusive outcomes and incomplete DAR/RAR to enter the peer review process.

ISSUE WITH SOIL METABOLITES LEACHING TO GROUND WATER

- An issue seems to be stemming regarding possible **metabolites** that haven't been considered during the peer review, because of the lack of proper **radio labelling**.
- Applicants make decisions on radio labelling, and then, the Peer Review checks on the components for which a label has been assigned. **In case the relevant compound is not labelled, the process fails to identify it.**
- Following discussions, Member States are kindly requested to **pay attention to the soil degradation experiments when they act as RMS**. The carbon atoms bound to the fluor atoms should always be radioactively labelled so that the degradation pathway and kinetics of this part of the molecule can be studied.

⇒ Again the **pre-submission meetings** may be a suitable forum to address the radiolabelling strategy based on the functional groups, the structures and the toxicity of the components, and avoid similar situations in the future.

FEEDBACK FROM COMPLETENESS CHECK - GAP

GAP Table

- The GAP sets out the details of the representative uses, therefore should be presented accurately to ensure appropriate risk assessment is undertaken:
  - The GAP table submitted in the DAR/RAR should be **clear** and presented in the **new format**;
  - The GAP table submitted in the DAR/RAR should be **consistent with the GAP in the dossier (Document D1)**;
  - The GAP in **Vol.1** should be in line with the GAP presented in the **LoEP**;
  - The GAP should **not be repeated in other parts of the DAR/RAR** to avoid that different GAP tables are presented in different sections of the DAR/RAR.
- EFSA Administrative Guidance: "***Changing the GAP forms*** *is* ***not permitted*** *during the ongoing* ***peer review*** *except for providing clarifications (e.g. as regards to the types of protected cropping systems / greenhouse structures) or correction of errors (e.g. correction in case of obvious mismatch between growth stage of last application and the proposed PHI, or error in calculation of concentration e.g. due to mismatch of units)*"

FEEDBACK FROM COMPLETENESS CHECK - GAP

- Before submitting the DAR/RAR to EFSA, the RMS should verify that the GAP in the DAR/RAR fulfills the previously mentioned criteria.
- During completeness check, EFSA verifies the above elements so that the risk assessment is conducted in all sections for the same GAP.
- During completeness check, EFSA regularly requests the RMS to submit the latest GAP Table contained in the D1 document which should be also presented in the latest format. This is done to verify the alignment with the dossier.
- The latest GAP table template is contained in the LoEP combined AR/CLH template: https://food.ec.europa.eu/document/download/5a067575-40fa-4fb3-93f1-640d0a8a6984_en?filename=pesticides_ppp_app-proc_guide_doss_12592-2012.zip

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*)
(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		

FEEDBACK FROM COMPLETENESS CHECK - STUDY SUMMARIES

- The Appendix E of the EFSA Administrative Guidance contains a 'Template for presenting individual studies' that should be used by the applicant in the summary dossier and by the RMS in the assessment report.
- The RMS should assess the individual studies for their acceptability and deviations to Test Guidelines and clearly present their view.

1. Information on the study
Data point:
Report author
Report year
Report title
Report No
Document No
Guidelines followed

2. Full summary of the study according to OECD format
This should include study description and study results presented in tabular fo
The study summary should contain a description of the study design and the
Materials and methods
Study description - Text / Tables / Figures
Results
Study results - Text / Tables / Figures

3. Assessment and conclusion
Assessment and conclusion by applicant:
Assessment and conclusion by RMS:

This applies also to non-guideline studies or scientific peer-reviewed publications.

WoE approach and independent assessment

FEEDBACK FROM COMPLETENESS CHECK – OTHER ISSUES

- Literature search presentation: to be presented in line with the template available as an appendix to the EFSA 2011 Guidance https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903/j.efsa.2011.2092&file=efs22092-sup-0001-Appendix.pdf
- Analytical methods: The "*Overview table for analytical methods used for risk assessment*" should be regularly included in Vol. 3 CA B5 and 3 CP B5.
- Representativeness of batches: The representativeness of batches in mamm tox and ecotox studies should be presented in Vol 4, section C.1.4. The RMS should include a table reporting the list of batches (see Appendix J of the EFSA Administrative Guidance). The RMS conclusion on the representativeness of the batches should be presented in Vol.4.
- Metabolites: The list of metabolites should be included in the DAR/RAR; it should reflect the information contained in the N3 document and be presented in Volume 1.
- Appendixes : to be submitted to EFSA together with the DAR/RAR volumes (if applicable):
  - PRIMo 3.1. excel file
  - Animal Model 2017 excel file
  - Appendix G (Residues)
  - Appendix E (ED)
  - MRL application form

NOTIFICATION OF STUDIES: UPDATE ON THE Q&A

Update of the Q&As on EFSA's Practical Arrangements (28 August 2023) – Question 4

- **Exemption** for **certain analytical measurements** from notification of study obligations:
  - analyses to assess the identity/composition of a product, including the determination of its impurities and whole genome sequencing
  - analyses to determine physico-chemical properties
- In addition, **method validation studies** are not considered to fall within the definition of study, given that they are not meant to obtain data with respect to the properties and/or the safety of the test item.
- The **NoS instructions for MSs** have been updated accordingly.

For any questions, please contact EFSA via the Ask a question tool

https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements

WHAT'S NEXT

EFSA is available to further support MSs working on the presented aspects

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

EFSA can support RMS in complex issues

EFSA can support RMS during the Completeness check and even during the admissibility process (for post-TR dossiers)

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