Action point from the 32nd Pesticides Steering Network

FOLLOW-UP ACTIONS FROM SURVEY TO MEMBER STATES

FDP UNIT

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SURVEY TO MEMBER STATES

Survey Launch

Targeted survey launched after the 32nd PSN meeting to gather feedback to identify potential solutions for improvement in several key areas. The survey ran from **3 December 2024** to **14 February 2025** via EU Survey.

Key Focus Areas

- Coordination of Member State activities with ECHA (biocides, REACH, classification and labelling);
- Pesticides Peer review expert meetings;
- Enhancing the quality of the dossiers in the field of pesticides;
- Enhancing the quality of the Assessment Reports in the field of pesticides;
- Resource constrains / difficulties;
- Ideas for improvement.

Respondents

16 responses were received from the following countries: **Austria, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Latvia, Lithuania, Netherlands, Portugal, Romania, Spain, Sweden and Norway,**

OVERVIEW OF THE TOPICS

- Coordination of Member State Activities with ECHA
- EFSA Pesticides Peer Review Expert Meetings
- Enhancing the Quality of Dossiers in the Field of Pesticides
- Preparation Phase of Assessment Reports
- Quality of Assessment Reports at Completeness Check Phase
- Quality of Updated Assessment Reports at Peer Review Stage
- Resource Constraints and Difficulties

QUALITY OF POST-TRANSPARENCY DOSSIERS

- FDP analysed the results of the survey with a focus on support to MS/applicants, dossier intake, completeness check of AR
- Main issue related to intake phase is the poor quality of dossier, however same issue impacts entire process
- Applications currently in peer-review are based on 'early phase IUCLID' dossiers' - dossier quality should improve in upcoming year

A set of actions/proposals has been already identified to address some of the issues raised:

- **Increased support to applicants**
- **Increased IUCLID validation assistant rules – business rules**
- **Improved Admissibility checklist**
- **Improved completeness check of AR**
- **Support to MSs and applicants on dossier**
- **More detailed guidance for applicants on dossier preparation**

Additional actions may be considered in the future to address other issues (e.g. on NOS) - more detailed analysis is needed to identify suitable options.

SUPPORT INITIATIVES TO APPLICANTS TO IMPROVE QUALITY OF DOSSIERS

- EFSA increasing direct support to applicants by attending conferences/third-party events with presentations and info-stands. Already confirmed for this year:
  - CropLife Europe MRL & Trade Workshop - 10-11 June 2025, Brussels
  - ABIM - Annual Biocontrol Industry Meeting - 20-22 October 2025, Basel

- Proposal to organise yearly ad hoc meetings with industry and MS representatives, in line with EFSA Catalogue of support initiatives to discuss methodological and procedural aspects and provide guidance to applicants on how to avoid recurrent issues
  - See Section of the Catalogue 2.5.5. Ad hoc meeting with food and feed business representatives

- In case of new active substances, proposal to increase pre-submission meetings, inviting systematically applicants to request them to RMS. EFSA to be invited by default to support RMS.
  - Administrative guidance to be updated in the future to reflect this proposal
  - RMS invited to already recommend applicants to take advantage of pre-submission meetings and to involve EFSA

SUPPORT INITIATIVES TO APPLICANTS TO IMPROVE QUALITY OF DOSSIERS

- Improving EFSA Applications webpage and release of more FAQs to better guide and inform applicants

- EFSA working on detailed guidance for applicants on dossier preparation:
  - Improved IUCLID manuals with May IUCLID release
  - Survey on manuals will be launched to collect improvement needs and ideas (September)

- EFSA liaising with industry associations to offer training opportunities to their members and increase understanding of requirements/specific issues
  - First contacts established with CLE, ABIM, ECCA, EACL

IMPROVING AUTOMATED DOSSIER VALIDATION

- Increase in validation assistant rules was reported as a way to improve the admissibility process and quality of dossier
- Currently 180 rules are in place, with approx. 10 new rules in May release and 30 more in October release
- At last PSN meeting MSs were invited to share the requests to the applicant during admissibility to help translating those requests into business/validation rules

In order to implement new rules EFSA needs specific proposals or alternatively MS should share their requests to applicants on missing parts of the dossier with FDP

IMPROVING ADMISSIBILITY CHECKLIST

- Admissibility check list has been improved adding new items as suggested in the survey (e.g. chemical and micro identifiers, excel file for PRIMo, appendix E for ED)
- Sections generated via IUCLID generator have been added (e.g. GAP, list of substances and metabolites, table of analytical methods)
- Relevant IUCLID section has been added to facilitate the search and check for information in IUCLID
- Invite MS to recommend applicant to apply the checklist as a final quality check before submitting the dossier

Not possible to check all information in detail at admissibility check	Not possible to check all information in detail at admissibility check. Full study reports might be absent (only protocols provided), or required data might be unavailable in editable/tabulated format.	1	33%

Category	Description	Frequency	Percentage
Checklist content	More comprehensive checklist that includes additional documents or data items (e.g., ED xls-file, PRIMo tables, links to templates, "FAQ" with common error messages, etc).	2	40%

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Category	Description	Frequency	Percentage
Missing or inadequate data	Critical data are missing or not sufficiently addressed in the dossier, even after passing admissibility checks.	10	30%

IMPROVING SUPPORT TO ADMISSIBILITY

Support to MS on dossiers:

- Reinforce the pre-admissibility TC – EFSA will proactively offer support depending on dossier(s) in pipeline (e.g. NAS, new substances, less experienced MS etc)
- Strengthen the MS tour – focus on MS with many admissibility pending or MSs that have less experience
- Ad-hoc meeting in support to other issues/difficulties (e.g technical issues)

COMPLETENESS CHECK (CC) OF ASSESSMENT REPORTS

- Most common re-work during CC flagged during the Survey (e.g. GAP, literature search, individual studies presentation, ED assessment) are key requirements for the peer-review and listed in the checklist and Administrative Guidance
- It is noted that formatting/editorial changes might be a burden -> EFSA is limiting the admin/editorial check to a minimum: this is an area where we applied a leaning approach. A further improvement based on the MS survey is on-going.
- Rework nr and frequency varies depending on the active -> microorganisms have less experimental studies, leaner assessment
- Separate comments from ECHA and EFSA: the Agencies work independently but we align timelines of Accordance and Completeness Check as much as possible, giving the highest priority to New Active Substances -> EFSA advises the RMS to address ECHA's and EFSA's feedback altogether and resubmit at the same time to the two Agencies

COMPLETENESS CHECK (CC) OF ASSESSMENT REPORTS

- In relation to the revision of **Guidance documents and templates** -> additional clarifications to be introduced in the EFSA Administrative GD. However, could you please indicate which elements need to be clarified in relation to the Assessment Report preparation?
- As for the **combined template**, it has been recently revised with the introduction of the new hazard classes -> where do you think it merits revision?
- Request for **standardized data presentation** thus ensuring uniformity and reducing rework -> having IUCLID dossier correctly filled-in will enable the generation of relevant parts of the AR through report generator. ECHA is finalizing the work on the CLH report (Vol.1) while EFSA is continuously working on report generator improvement (pls refer to the IUCLID PSN for more updates). This connects to better quality dossier -> a revised Admissibility checklist is soon to be published.
- **Specialized tools** (e.g., calculation aids) to facilitate a consistent, robust approach to data evaluation -> can you please provide examples of tools or specify needs?