

35th Pesticide Steering Network Meeting, 12 May 2026

METAPATH PRACTICAL USE, CHALLENGES AND SUPPORT NEEDS

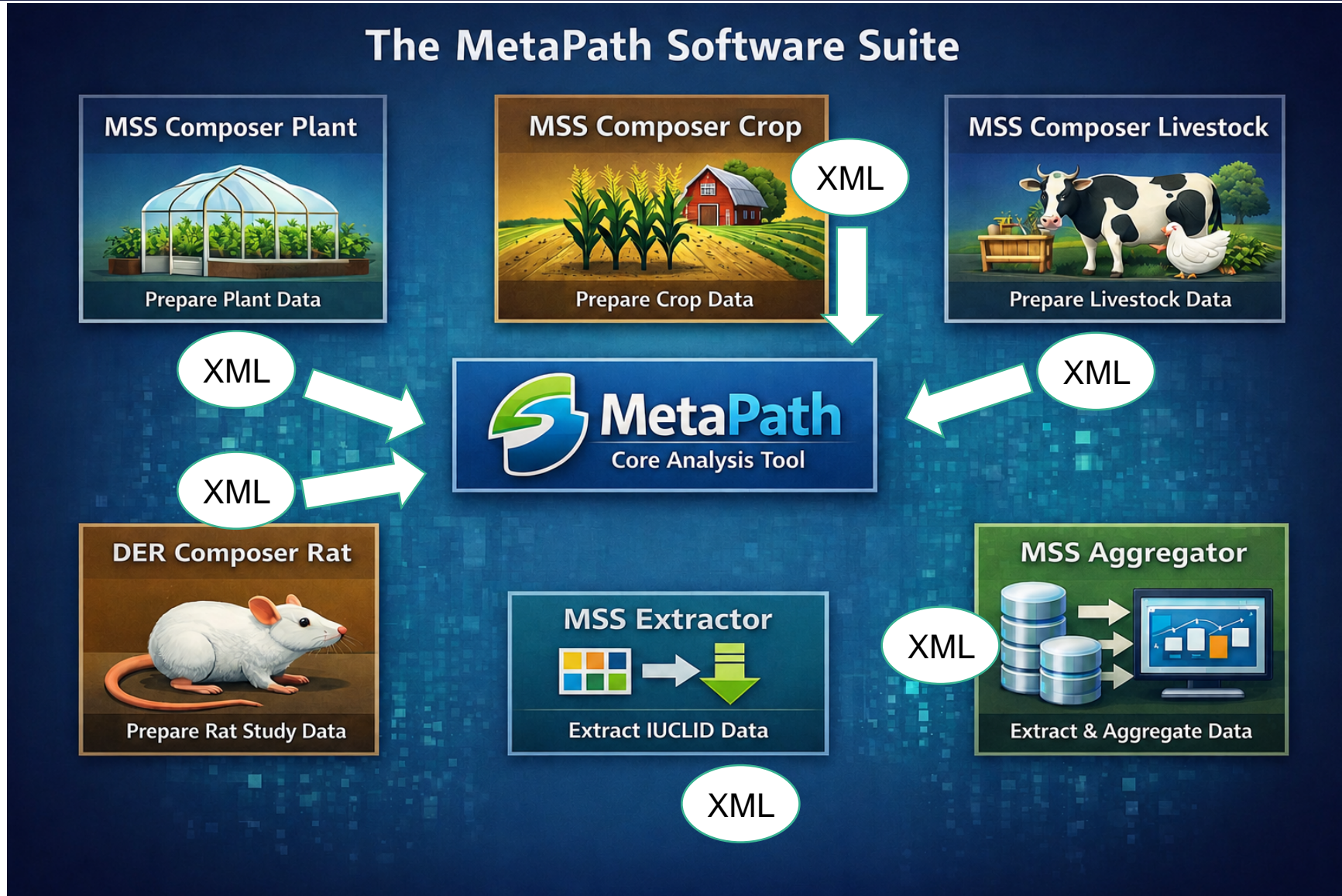


AIM & SCOPE

- This presentation responds to questions raised by Member States on the implementation and use of MetaPath and MSS/DER Composers, including quality assurance for received data files.
- EFSA will also present a survey outcome, clarify regulatory and procedural points for structured data submission, and provide an overview of existing support material as well as ongoing and future activities related to MetaPath.



SETTING THE SCENE AGAIN



SURVEY: METAPATH & QA IMPLEMENTATION STATUS

MS FEEDBACK

Feedback from **13 Member States** on the implementation and use of MetaPath & MSS/DER Composers reveals low adoption and inconsistent QA practices.

Implementation Status MetaPath

9 MS (69%)

Not implemented

2 MS (15%)

Partially implemented
(testing / limited use)

2 MS (15%)

Fully implemented (routine use)

QA Checks on MSS/DER Files

10 MS (77%)

Not performed / unclear if or when required

2 MS (15%)

Performed occasionally / not routine

1 MS (8%)

Performed routinely (clear process)



SURVEY: METAPATH USE, BENEFITS & MAIN CHALLENGES

MS FEEDBACK

QUESTION 3

Use & Perceived Value of MetaPath

12 MS (92%)

Not used / no clear benefit

1 MS (8%)

Used occasionally / some benefit

0 MS

Used routinely / clear benefit

Main Challenges Reported

Single-choice responses from the survey:

38%

Technical / operational issues (tools, validation, workflows)

31%

Lack of clarity (QA requirements, scope, timelines, future steps)

31%

Workload / resource burden



AVAILABLE SUPPORT MATERIAL

Since 2021, EFSA has provided a range of support materials for MSs and applicants covering MSS/DER Composers, MetaPath, and process guidance.

Resource	Description	Audience
MSS/DER Composer Manuals	Manual for MSs and applicants	MSs, Applicants
Webinars: MSS & DER Composers	Recordings + presentations (plants, livestock, rotational crops; rat data)	Applicants
Info Session: MSS XML Validation	Event recording, agenda, presentations, Q&A, QA templates	MSs
MetaPath Video Tutorials	Introductory (Ch. 1–5), Intermediate (Ch. 6–10), Advanced (Ch. 11–13), Specialised topics (Ch. 14–16)	MSs, Applicants
EFSA MetaPath Database	Database of > 1200 metabolic maps	MSs, Applicants
Regulatory Legacy Database	List of maps (Database access for MSs)	MSs, Applicants
Workflow Guidance & FAQ	Process guidance (Sections 3.2, 3.4, 3.5); MetaPath FAQ (Zenodo); IUCLID backlog file	MSs, Applicants



IS THE QA CHECK FOR XMLS MANDATORY FOR RMS?

QUESTION 1

Is the QA check mandatory for RMSs?

If yes, is it applicable for all substances under evaluation or is there a cut-off date?

- ① There is **no cut-off date** after which RMS QA checks of MSS/DER composers become mandatory. Under the transition to IUCLID submissions (from **27 March 2021**), RMSs are required to perform a completeness check using the IUCLID Validation Assistant and Report Generator, complemented by manual checks of attachments not covered by these tools.

MSS/DER composers fall under this category of attachments; therefore, their verification is part of the general completeness and admissibility assessment (See Step 1, completeness check).

Reference: Appendix C to the Administrative Guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure (EFSA, 2021, DOI: 10.2903/sp.efsa.2021.EN-6464).



WHAT IS THE CURRENT STATUS OF THE DATABASE & QA CHECKS ?

QUESTION 4

Observed compatibility challenges align with a low adoption rate of QA checks demonstrated by the survey outcome.

1,281

Maps in Database

Total QA maps in the public EFSA MetaPath database

~400

Active Substance XMLs

XML files submitted via IUCLID for active substances

~50

MRL XMLs

XML files submitted via IUCLID for MRLs

50-60%

Incompatible

XML files affected by technical and procedural factors, including QA variability



WHAT ARE THE BENEFITS OF METAPATH FOR MS?

QUESTION 2

MetaPath converts unstructured metabolism studies into organised, searchable datasets for plants, livestock, and rats, allowing comparison of metabolic pathways across substances.



Search & Comparison

Identify common metabolites; search and compare chemical structures and sub-structures (e.g., TFA moiety); detect and visually compare shared transformation pathways.



Kinetic Layer Function

Links metabolic pathways to kinetic information for rat data, enabling interpretation of relative formation, persistence, and progression of metabolites (e.g., via half-life or concentration–time data).



Targeted Queries

Inform combined searches e.g., all available studies on fish for substances containing a specific structural feature, e.g. aniline moiety



Data Extracts & Reports

Generate data extracts and summary reports (Word & Excel) from both MetaPath and MSS Composer XML files.



MetaPath is a tool supporting risk assessments, through better organisation and analysis of metabolism data.



METAPATH IN THE BROADER REGULATORY LANDSCAPE

Strong interest in MetaPath in OECD expert discussions on regulatory IT tools.



MetaPath User Group

Convenes biannually for discussions and updates between regulatory bodies and industry users



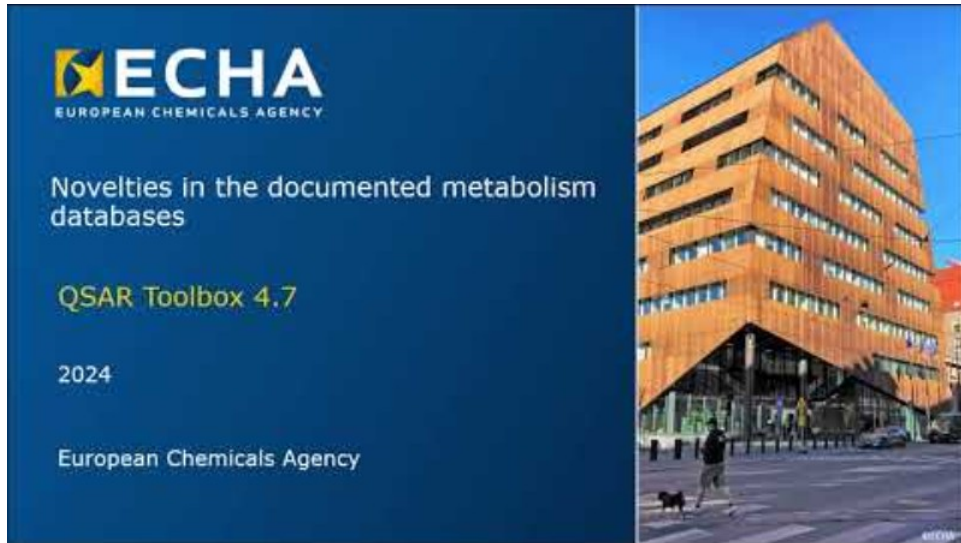
QSAR Toolbox Management Group

MetaPath discussed **together with IUCLID and QSAR Toolbox** as part of an integrated tool ecosystem.

Emphasis on:

- **interoperability** between tools,
- **alignment of metabolism data**,
- **avoidance of duplication** in regulatory workflows.

OECD experts highlighted the need for clearer process descriptions of **data workflows** involving MetaPath.



SUMMARY & LOOKING AHEAD

Role of MetaPath

MetaPath should have a clearly defined role in EFSA/MS evaluations.

MetaPath is **not an additional reporting exercise**, but a toolbox to:

- Structure complex metabolism data
- Support consistency and traceability in evaluations
- Enable cross-substance and cross-study analysis not feasible with PDFs alone

MSS/DER Composer XML files are the **technical bridge** between applicants' studies, IUCLID submissions, and MetaPath

What About the Future?

QUESTION 5

- There are **no plans** for a modern MSS Composer for rat metabolism.
- MSS/DER Composer tools will be **phased out**. Current use should be seen as a **transitional step**, not the final workflow.
- Metabolism data will be entered directly in **IUCLID** and transferred to MetaPath — project ongoing until **mid-2027**.
- MetaPath data will support a **semi-automated workflow in the QSAR Toolbox** for residue categorisation and toxicological assessment of metabolites (new OECD guidance on Res. definitions).



Strategic relevance is growing internationally, while anchoring in EU day-to-day evaluations is still needed.



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