

20<sup>th</sup> April 2021

# Webinar: MetaPath – how to complete DER composers for pesticides mammalian toxicology metabolism studies

14.00-18.00 Parma (IT) time  
7.00-11.00 Duluth (USA) time

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TIME	ITEM
14:00-14.15	<b>Introduction &amp; presentation of the project</b>
14:15-15:00	<b>Opening DER</b> <b>General info</b> <b>Material and methods</b> -Theory -Live demo of data entry -Summary key points -Q&A
15:00-15:45	<b>Appendix 1a and Appendix 2</b> <b>Material and methods.</b> <b>Study design</b> -Theory -Live demo of data entry -Summary key points -Q&A
15:55-16:10	Coffee break
16:10-16:55	<b>Results – Pharmacokinetic studies</b> -Theory -Live demo of data entry -Summary key points -Q&A
16:55-17:40	<b>Results – Metabolite characterization studies</b> Conclusions Theory Live demo of data entry Summary key points Q&A
17.40-18.00	<b>Key points -Data Entry Flowchart</b> Q&A

Speaker: Juan Manuel Parra (EFSA)

Speaker: Richard Kolanczyk (US EPA)

Moderator: Martina Panzarea (EFSA)

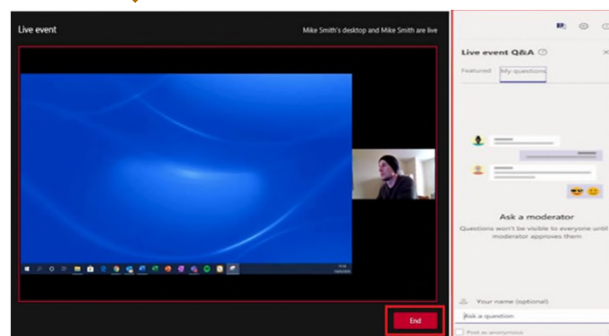
IT Support: Carla Dall'Aglio and  
Alberto Goldoni (EFSA)

Events Team: Francesco Amoretti  
(EFSA)

# Webinar guide for attendees

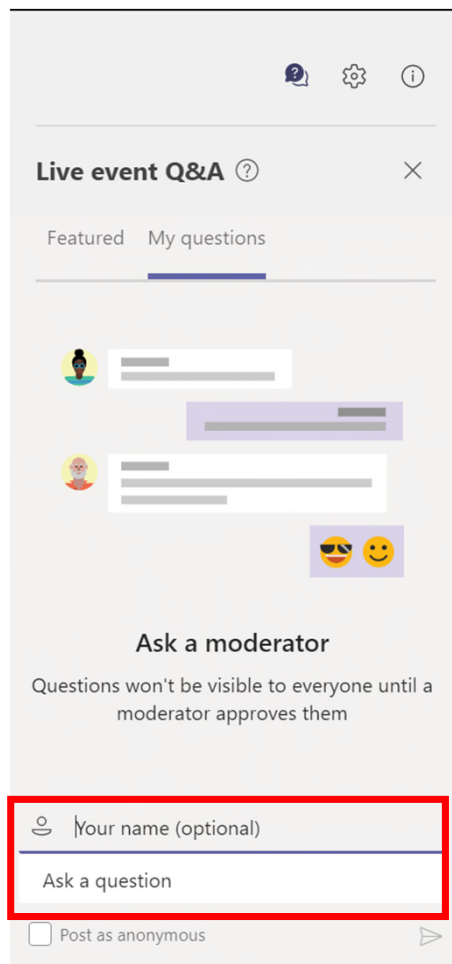
- This webinar **is being recorded**
- The webinar **is in English** and questions should be submitted in English through the platform (see hereunder).
- You are automatically connected to the audio broadcast. One-way audio (listen only mode).

Presentation window



**Q&A box:**  
For any questions related to the topic or unexpected IT issues

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e.g. Juan Parra (EFSA)

P: Material and methods: Are all the DER fields mandatory?

Procedural (P)

Manual

Technical (T)

Webinar

20th April 2021

# Introduction and presentation of the project MetaPath

**Juan Manuel Parra Morte**

Toxicologist Pesticide Peer Review Unit

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- Why?
- What?
- Who?

# Why are we here?

- According to the EU data requirements on pesticides, metabolism studies are required in several areas:
  - Toxicology: Lab species (e.g. rat)
  - Residues: Plants (e.g. maize) or Livestock (e.g. goat)





# Why are we here?

Contract Research Organisation  
(CRO)/Academia

Industry

Risk Assessors

Computational toxicologist

Public

- Conduct the studies
- Sponsor the studies
- Assess the studies
- Predict the outcome
- See how studies are assessed

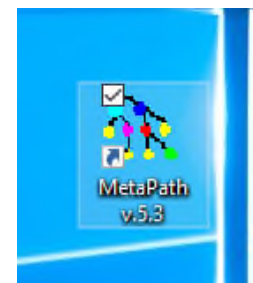
#metabolism





# Why are we here?

- Transparency Regulation:
  - EFSA has new requirements for capturing, managing, handling and distributing data on plant protection products (PPP).
  - Use of **IUCLID** (managed by the European Chemicals Agency – ECHA)
  - Furthermore, applicants should provide data on metabolism in the areas of residues and mammalian toxicology as attachments generated with the **MetaPath** software package



# What is Metabolic Pathways ?

- Purpose
- Freely available software:
  - Data analysis ("MetaPath")
  - Data entry ("Composers")
- Electronic databases

*Archiving, sharing and analyzing experimental data on metabolism, metabolic pathways and crucial supporting metadata.*

<https://oasis-lmc.org/products/software/metapath.aspx>

1) Regulatory Legacy collection of maps.

2) EFSA Public collection of maps

<https://www.efsa.europa.eu/en/applications/pesticides/tools>

# What is MetaPath?

Data: metabolism studies

Composers

xml files

MetaPath

Database

Comparison tools

Prediction

Experimental data



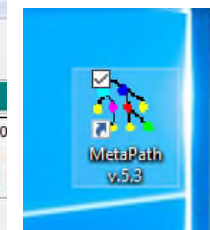
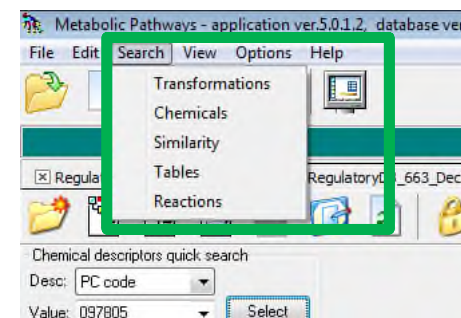
Data entry



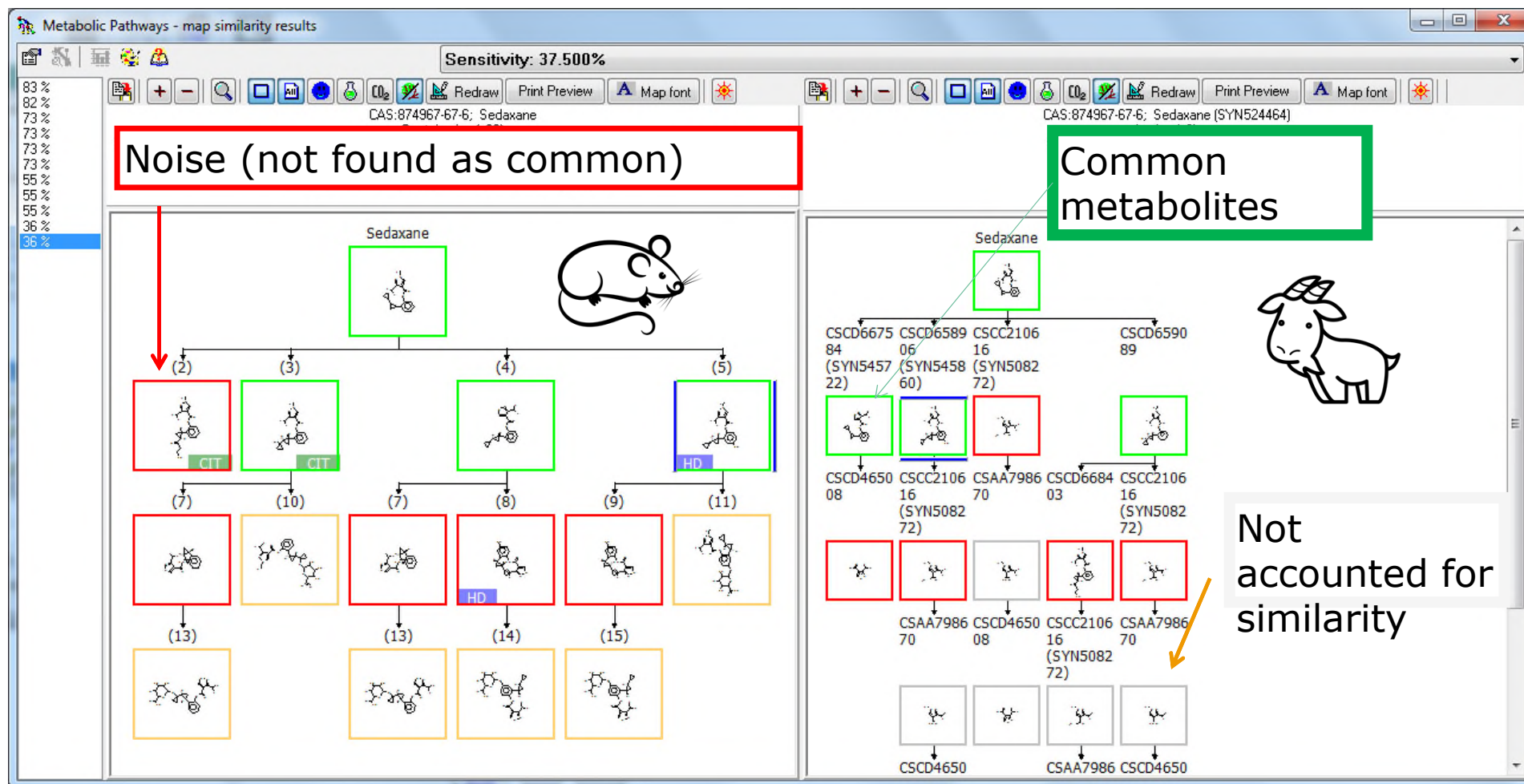
Electronic submission (attachment)



Risk assessment



# What is MetaPath?



# What is MetaPath?



- Composers: data entry software

- Metabolism Study Summaries (MSS)



<https://www.efsa.europa.eu/en/events/event/metapath-how-complete-mss-composers-pesticides-metabolism-studies>

- Data Evaluation Record (DER)



*Customized screen editors developed to automate data entry into MetaPath while also streamlining the production of agency specific study summaries such as the Data Evaluation Records (DER) used by the US EPA Office of Pesticide Programs*

# What is MetaPath?



- International collaboration:
  - OECD MetaPath User Group (MUG): industry, regulatory agencies around the world.
  - EFSA joined some years ago.
  - Born in the USA, with the US EPA leadership in collaboration with Laboratory of Mathematical Chemistry (LMC).

# Who?

- Richard C. Kolanczyk
- U.S. EPA Mid-Continent Ecology Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development (ORD)



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