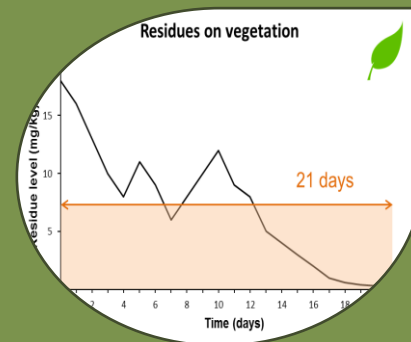


# 3rd Virtual Workshop on the revised EFSA Birds and Mammals Guidance Document

Background, Regulatory hurdles, Ambiguities, Lines of evidence, Modelling – How best to approach the new fTWA assessment.



April 28, 2026



10 am – 3 pm CET

***Felix von Blanckenhagen – RIFCON***

**Introduction**



**RIFCON**



**CropLife**  
EUROPE

# Aim of this workshop

## Discussion topics

- Background of the fTWA evaluation according to EFSA (2023).
- Regulatory implementation of fTWA evaluations for birds and mammals.
- Ambiguities in the EFSA 2023 guidance on fTWA evaluations for birds and mammals.
- Non-modelling and modelling lines of evidence that may be useful in fTWA evaluations.

# Aim of this workshop

## Key questions

- To what extent does fTWA influence the outcomes of risk assessments for birds and mammals?
- Are fTWA evaluations challenging from both regulatory and technical perspectives?
  - Regulatory: How can a transparent fTWA evaluation process involving all stakeholders be established, including submission of additional data?
  - Technical: Does an fTWA evaluation require in-depth data analysis and potentially additional lines of evidence?

# Schedule

## First section

10:00	Welcome and Agenda	Steven Kragten (CLE) Felix von Blanckenhagen (RIFON)
10:10	Background of fTWA evaluation	Jens Schabacker (RIFCON)
10:30	Regulatory hurdles	Manousos Foudoulakis (CLE)
10:50	Questions	
11:00	Breakout groups	

## Second section

11:15	Ambiguities of fTWA evaluation	Michail Gioutlakis (RIFCON)
11:50	Questions	
12:00	Breakout groups	

**12:15 – 12:45 Lunch break**

# Schedule

## Third section

12:45	Summary breakout session 1	Jan-Dieter Ludwigs (RIFCON)
12:55	Summary breakout session 2	Kaat Brulez (RIFCON)
13:05	Non-modelling lines of evidence	Steph Plautz (CLE)
13:35	Questions	
13:40	Modelling lines of evidence	Thomas Martin (RIFCON)
14:10	Questions	
14:15	Breakout groups	
14:30	Summary breakout session 3	
14:40	Final Remarks	Felix von Blanckenhagen (RIFON) Steven Kragten (CLE)
15:00	THE END	

# Key message: It's complex

## **From a regulatory perspective (for product dossiers)...**

- Concerns: consistency in evaluations, transparency, ability to submit additional information if needed
- Transparency for all stakeholders? Involvement of data owner?

## **From a technical perspective**

- Studies and endpoints to evaluate for product dossiers are uncertain
- Standard studies typically cannot provide information on time to effect
- Additional lines of evidence may be helpful, but acceptability is uncertain

## **Main issue**

- Predictability of outcome of fTWA evaluations is low, but might have significant impact on risk assessments

# Proposal



## **EU level: Conduct full fTWA evaluation with endpoint evaluation**

- In-depth data analysis in parallel with the endpoint derivation
- Ecological relevance of effects from all studies considered relevant according to EFSA 2023 evaluated and decided on EU level
- Discussion of fTWA evaluation with RMS during pre-submission meetings gives time to prepare higher tier strategy or additional lines of evidence if needed
- Additional data submission possible within the process if needed
- All stakeholders involved in the commenting process
- Meaningful generation of higher tier data for product submission possible (focus on residue decline studies or other higher tier options?)

## **Products: Use decision on fTWA use in most recent EFSA conclusion in issue**

- fTWA was not used when evidence showed short-term exposure driving effects

# Thank You

## Meet again at SETAC 2026 in Maastricht

- **CLE lunch Seminar 19th of May 2026, 13:00 – 15:00, Room 1.1 Level 1**
  - Sponsored Lunch Seminar: The new EFSA Birds and Mammals Guidance Document: Ready for take off?
- **RIFCON, discuss your question 1:1 in our meeting room 2.5 on Level 2 of the auditorium on Wednesday 20 May. Book a slot via LinkedIn!**

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