



Workshop minutes

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

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RIFCON **CropLife EUROPE**

Registration closes on 31st March 2026

The poster features a green background with a white border. It includes a small line graph titled "Residues on vegetation" showing a peak and then a decline over 21 days. There are also images of a brown mouse and a small bird perched on a branch.

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1 Introduction

The third online workshop, held on 28 April 2026 and initiated by CLE, was titled “Background, Regulatory Hurdles, Ambiguities, Lines of Evidence, Modelling – How Best to Approach the New fTWA (time-weighted-average factor) Assessment.” The workshop aimed to bring together all stakeholders involved in the registration of pesticides, with a particular focus on bird and mammal risk assessment.

The new Bird and Mammal Guidance (EFSA 2023), which entered into force on 1 October 2025, introduces numerous new topics and challenges for risk assessment. One major topic is the applicability of the fTWA, and therefore the use of residue decline data for the diet of birds and mammals. This requires a careful evaluation of the underlying toxicity data. Based on the ecologically relevant endpoint for the reproductive risk assessment, it must be determined whether the reproductive effect defining the endpoint is driven by short-term or long-term exposure.

If the endpoint reflects a toxic effect due to long-term exposure, the fTWA can be applied in the reproductive risk assessment for long-term exposure scenarios. However, if the endpoint is based on reproductive toxicity due to short-term exposure, the fTWA cannot be applied in the reproductive risk assessment, which has a major impact.

The workshop provided insight into the background of the fTWA evaluation, its ambiguities, emerging regulatory hurdles, and additional lines of evidence. It addressed the daily challenges faced by risk evaluators, as reflected in the strong interest and broad participation.

Outreach of fTWA workshop 28 April 2026

- **~ 200 interested & 150 participants**
- **Authorities, Academia, Industry, Consultancy, CROs**
- **From 27 countries**
- **From 6 continents**

2 Overview and outline

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.

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?

Presentations:

During the presentation, questions and answers (Q&A) were collected from the audience via Q&A chat. All questions were addressed in the minutes, including those that were not answered by the presenter during the workshop.

- 1) Background of fTWA evaluation (Jens Schabacker, RIFCON)
- 2) Regulatory hurdles (Manousos Foudoulakis, CLE)
- 3) Ambiguities (Michail Gioutlakis, RIFCON)
- 4) Non-modelling line of evidence (Steph Plautz, CLE)
- 5) Modelling line of evidence (Thomas Martin, RIFCON)

Breakout sessions

Between the presentations 3 breakout sessions were conducted. Each breakout group consisted of two moderators, one from CLE and one from RIFCON and 25 participants.

- I) Background and regulatory hurdles
- II) Ambiguities
- III) Additional lines of evidence

Breakout groups

Breakout group	Moderator RIFCON	Moderator CLE
1	Jan-Dieter Ludwigs	Neil Sherborne
2	Ivona Trajcheska	Steph Plautz
3	Kaat Brulez	Katharina Ott
4	Carola Fink-Schabacker	Manousos Foudoulakis
5	Jochen Gerlach	Steven Kragten
6	Martin Vallon	Arnd Weyers Markus Ebeling

3 Background and regulatory hurdles

3.1 Q&A: Background of the fTWA

Questions from the audience

1. When data is not enough to produce the assessment for the use of fTWA (e.g., using data published in EFSA Peer Review) what should be done: produce more studies (here you have the problem of testing with vertebrates)? Or are there any other possibilities?

Answer:

Approach the data owner, for access to the full study reports, or ask for their participation, because it is also in the interest of the data owner to have a fully justified evaluation. However, in clear cases the data from the EFSA RAR might be enough and the topic can be addressed in 2-3 working days. In more complex cases, full study reports are helpful. Aligning with toxicity chapter is always recommended. New studies should not be routinely conducted in order to reduce vertebrate testing and may only be considered as a last resort. For other possibilities refer to later presentations.

2. In case fTWA cannot be applied in the risk assessment, can DT₅₀ data be used to refine or mitigate the risk?

Answer:

Even if the DT₅₀ data cannot be used to refine the fTWA, DT₅₀ can still be used for the calculation of the multi-application factor (MAF). However, the outcome of the future evaluation will determine whether it can be used as mitigation of the risk

3.2 Q&A: Regulatory hurdles

Questions from the audience

1. Although it makes absolutely sense to assess the twa only at the a.s. level (AIR or new a.s.) together with the endpoint, as the current status at the product level is indeed very complicated, what would be the process if the omnibus takes place and renewals are paused indefinitely? When will the EU agreed fTWAs in that case be assessed for actives that have just been renewed without an agreed conclusion on the fTWA?

Answer:

The omnibus procedure proposes ways to streamline EU processes. For pesticides, this means, for example, no renewals of active substances needed if they are approved once. This draft legislation just hits the EU parliament, so the outcome of this process is far in the future and not predictable now. This directly hints on the problematic process. With the process of the evaluation of the fTWA a lot of uncertainties arise regarding timelines and competences. Currently it is not possible to predict, how the fTWA influences the registration process. According to the PAI document published in September 2025, a fTWA evaluation should take place in the context of (renewal of) approval of active substances and in the context of (renewal of) authorisation of plant protection products.

2. The last EU agreed conclusion will show if or if not, TWA had been applied?

Answer:

Yes, which is already nowadays the case if it is clearly shown that short-term exposure could lead to long-term toxicity. If it is done on product level, final RR and reporting table will be made available on CIRCABC and an addendum to the D(R)AR.

3.3 Breakout session I: Background and regulatory hurdles

- In terms of procedure, it is largely unclear what can and should be done for both active and mixture partners (combined risk assessment in mixture products). There are concerns over feasibility of the procedure, as it was raised in the presentation on regulatory hurdles.
- In addition, it is not clear if and how additional data can be submitted later in the process (especially in case the fTWA is challenged during the process)
- In terms of technical evaluation at product-level, there is a lack of clarity on which dataset should be used for TWA justification
- It is acceptable to impose restrictions (as in aquatic for example) where the data supports it.
- Point was made that risk assessment can be done without fTWA. Others replied with concern that for many compounds the higher tier refinement is based on substance-specific residue decline data. The need to switch to other options would be demanding time- and money-wise. Further, it is difficult to decide on that for a wide range of substances in parallel with the low predictability of the outcome of the fTWA evaluation. On the other hand, there will likely be different (or possibly identical) assessments based on different data – which will mean ‘more work’ over time for everyone involved.

- But how can clarity and a clear assessment be achieved when there are differing data sets and assessments that are not being shared? The desired route towards this clarity is for decisions to be made at an EU level - That is the core problem that has been identified.
- Concerns were raised how 3rd parties can provide fTWA assessments without access to the study reports.
- The hope is that a 'solution' can be found in near future (e.g. PAI Meetings), based on the discussions.
- CRD considering adopting the EFSA 2023 guidance but has decided to not evaluate fTWA at product level – it is proposed to also take this approach.
- Product registrations may be delayed, or registration cycle will likely slow down - Limited human resources in authorities are critical.
- Feedback from product meetings that assessments should be done first without fTWA, then evaluate risk assessment using fTWA if it fails without fTWA. However, following this approach what counts for decision-making on registration?
- Dataset for biologicals is very limited, therefore often it can be assumed that fTWA can't be used. However, biologicals usually degrade very rapidly and exposure isn't long term. A larger dataset may be needed to address exposure duration required to trigger effects.
- Curious how will zRMS communicate and coordinate
- Transparency would be highly relevant.
- In case ecological relevance is not discussed for studies within 3x, do those and the ecological-relevance discussion need to be included in the fTWA evaluation?

4 Ambiguities

4.1 Q&A: Ambiguities

Questions from the audience

1. Case where the fTWA is applicable and there is a higher ecologically relevant endpoint (within 3x of the lowest endpoint): Does this refer to ecologically relevant endpoints in the same (initially selected study) and additional relevant avian/mammalian tox studies?

Answer:

In this case two risk assessment should be calculated: one with the lower endpoint and a TWA and one with the higher endpoint without the fTWA. The guidance states the following:

“If the lowest ecologically relevant endpoint allows the use of the fTWA, it should also be checked whether a higher ecologically relevant endpoint (within 3x of the lowest endpoint) would not be appropriate with the fTWA, and if so, in that case a risk assessment should be presented using each endpoint.”

The guidance document is not specifying if this criterion should be applied only by considering the same study or the whole toxicological data package. We interpret it as all available mammalian studies need to be considered.

2. Remark to the issue of 3xhigher EP (endpoint): most probably this issue is indicated only in mammalian decision scheme because for mammals the overall ecologically relevant EP is derived based on the number of different types of long-term studies with separate ecologically relevant EP concluded separately for each type of study. For birds, there is only one type of the long-term study and it is not possible to have several ecologically relevant endpoints.

Answer:

For birds general fewer studies are available which might be relevant for the bird risk assessment. In most cases 1-2 bird reproductive studies are available which needs to be checked for relevant endpoints. However, within the study several reproductive endpoints are possible, and the ecological relevant one needs to be defined. Furthermore, there might be different ecologically relevant endpoints in many available studies and in that case, the 3x higher endpoint criterion has to consider them all. Overall, in general it is less work to address the relevant endpoint for birds compared to the large dataset for mammals, but a case-by-case consideration of the available data is necessary.

3. Given all these ambiguities and contradictions, will there be an initiative to update / revise the guidance document from EFSA 2023?

Answer:

Currently the only initiative is started by CLE, however the member states try to harmonise, but this process might take long.

4. Should additional endpoints (within 3x the lowest) also be considered if non-applicability of fTWA makes them more worst case only at higher Tier (i.e. after consideration of residue decline data)?

Answer:

Please note that up to now there is no feedback yet from authorities and therefore we are trying to interpret the guidance correctly. When we start receiving feedback, we will have more experience with the way authorities interpret it.

If there is an endpoint within 3x of the lowest, which does not allow the use of the fTWA, then 2 risk assessments should be presented, already starting at tier 1. One with the lower endpoint, for which a fTWA is applicable and one with the higher endpoint without the fTWA.

The way we currently interpret the guidance document is that we have to apply this criterion irrespective of the outcome of the higher tier risk assessment. If two risk assessments need to be presented and one of them or both need to be refined, then higher tier risk assessments are needed to prove an acceptable risk.

5. Would the question whether there are higher endpoints for wild mammals not be included in the wild mammal endpoint justification? This justification should look at the complete set of relevant tox studies?

Answer:

This would be desirable, but in general the evaluation is done only until the lowest ecological is defined, hence higher endpoints are often not checked for ecological relevance.

6. Should timings of applications be considered for birds? They may be outside of the breeding window.

Answer:

Good question, however breeding season is relevant for the whole reproductive risk assessment. It might be a weight of evidence argument that reproductive exposure can be excluded due to no reproductive activity in autumn. However, this needs to be discussed and justified.

4.2 Breakout session II: Ambiguities

- The suitability of using a time-weighted average (TWA) must be determined on a case-by-case basis.
- Uncertainty is created via inconsistencies between the EFSA 2023 guidance text and its flowcharts, particularly regarding applicability to birds versus mammals.
- The importance of ensuring that conclusions from product-level assessments become accessible to all stakeholders.
- Overall, the discussion reflected a shared need for clearer definitions, harmonised interpretation, and practical guidance to support consistent implementation of the EFSA 2023 framework.
- Technical ambiguities:
 - timing of applications relative to bird breeding behaviour
 - whether reproductive risk assessment is relevant in certain cases
 - how to interpret “short-term”
 - how mammalian studies can be used for the decision on birds
- Disagreement with the comment that for birds there is usually only one relevant endpoint as there are often reproductive studies with multiple species showing different toxicological effects.
- Additional uncertainties were raised around distinguishing primary versus secondary effects in bird studies. Uncertainty about type and severity of parental effects to decide if repro/development effect is primary or secondary. Further, how mammalian data could be used to support interpretation of avian effects.
- Uncertainty about definition of chick development
- There seems still a lot of uncertainty in how evaluations should and will be done.

5 Additional lines of evidence

5.1 Q&A: Non-Modelling lines of evidence

Questions from the audience

1. Is for many substance additional data like laying hen study available?

Answer:

Livestock feeding studies are generally required where significant residues occur in crops or commodities fed to animals and metabolism studies indicate that significant residues (> 0.01 mg/kg) may occur in edible tissues or that the potential for bioaccumulation exists. Hence, not for all active substances such studies are available.

2. Should recovery studies be restricted to quail, due to the natural tail off in breeding seen with mallard?

Answer:

True, it depends on the species, mallards typically lay eggs for 8 weeks. In the OECD 503 (Metabolism in Livestock) and 505 (Residues in Livestock) guidances it is indicated that the studies will run several weeks for OECD 505 e.g. at least 4 weeks. Therefore, it needs to be clarified if a recovery period of several weeks can be added considering the test species.

5.2 Q&A: Modelling lines of evidence

Questions from the audience

1. The presenter said repeatedly that models cannot prove anything, but they provide weight of evidence.

Answer:

Depending on the input data, modelling can give reasonable predictions, offering insights that standard statistical analysis cannot, hence they can be used on a weight of evidence basis. The quality and reliability of the predictions is dependent on the quality of the input data.

2. Would a further discussion on GMP -good modelling practise- (concerning documentation, transparency etc.) help to advance modelling as one line of evidence?

Answer:

Numerous developments in modelling for pesticide registration are currently underway. Continued dialogue among all stakeholders is therefore essential and should be actively encouraged to strengthen both understanding and acceptance of modelling approaches.

5.3 Breakout session III: Additional lines of evidence

- It was mentioned that if such “non modelling and modelling approaches for fTWA assessment” are used and need to be evaluated, this would even more underline the need to do this on EU level (complexity of the matter).

5.3.1 Non-modelling:

- Discussion about LD₅₀/10: The factor of 10 is based on a dataset that included organophosphates and carbamates, which are banned by now. Currently registered pesticides generally show lower toxicity to birds, so the factor of 10 should be re-considered by a more up-to-date dataset of today registered substances. Further with respect to fTWA evaluation, a substance-specific evaluation of sublethal effects would be reasonable.
- Can 6-week reproduction screen data support use of fTWA? A participant highly questioned the suitability of non-GLP data in general. Others considered the studies as relevant for the discussion. Although level and quality of reporting might be questionable. Mammals can be applied, but avian might be trickier. Laboratories are usually very detailed in reporting data in screening studies, would even better under GLP. Still the reliability of these data can be evaluated using the Klimisch score or comparable methods.
- The 3Rs principles in animal welfare (Replace, Reduce, Refine) limit the possibility of carrying out new animal studies.
- Acceptance of egg injection studies will be challenging.

5.3.2 Modelling:

- Participants stated limited to no experience with modelling approaches.
- Models are flexible and can be adjusted to application patterns
- Actual examples using the model to simulate exposure: yes & no. There have been clear examples in the past on how to apply these models, but not actually

on fTWA. In general modelling has been used as weight of evidence, but regulatory acceptance is uncertain and will depend on the evaluator.

- Lack of concrete guidance on how to apply, validate and calibrate the models. Specific guidance would be very helpful: a more standardized communication on what has been done on the topic. EFSA is preparing a guidance.
- From evaluators side, very detailed information to be provided on literature search and selection of input parameter values, make it understandable for the evaluators, clear reporting and descriptive process beside the scripts and calculations would be very helpful for all parties.
- Opinion from authority was that modelling lines of evidence are more promising when TER is close to trigger.
- Modelling can add lines of evidence, but acceptance is unknown, because validation is challenging for authorities, when expertise is missing. Therefore, more education or training opportunities for regulators from EFSA (or also CROs) would be good to increase the knowledge about modelling.

6 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 (e.g. avian reproduction studies) or do not exist (e.g. metabolite reproductive risk assessment)
- 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 peer review 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 in most recent EFSA conclusion in issue, pending the outcome of the EU peer-review process and aligning with toxicity endpoint evaluation (Benchmark Dose) process. The fTWA was already not applied in cases where evidence demonstrated that the reproductive effect was driven by short-term exposure.