NAVIGATING EFSA'S REVISED BIRDS AND MAMMALS GUIDANCE

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The European Food Safety Authority (EFSA) has updated its guidance on assessing the risks that plant protection products (PPPs) pose to birds and mammals (EFSA Journal 2023;21(2):7790). These revisions reflect regulatory and scientific developments, incorporate feedback on the previous guidance, and aim to harmonise higher-tier methodologies. A new calculator tool is also available to support risk assessments and improve consistency in application.

This update brings significant changes that will impact pesticide companies operating within the EU. It introduces more refined approaches to exposure and effect assessments, requiring businesses to adapt their strategies to remain compliant in an increasingly complex regulatory environment.

The revised guidance applies to dossiers submitted from October 2025 onwards, covering both the approval (or renewal of approval) of active substances and the authorisation (or renewal of authorisation) of PPPs under Regulation (EC) No. 1107/2009. However, for PPPs, there may be zonal differences in how the guidance is applied – an important factor for companies to consider when planning submissions.

What is the practical impact of the changes?

The revised guidance adopts a tiered approach for both exposure and effect assessments, beginning with conservative screening and advancing through refined modelling using species-specific data, the option to apply toxicokinetic-toxicodynamic (TKTD) models and – at the highest level – field effect studies. Every level of the assessment should be able to address the operational protection goals as detailed in the guidance.

Key changes from the previous guidance include clearer definitions of the ecological relevance of toxicity studies and endpoints, the use of indicator model species (IMS) and generic model species (GMS), with an increase in the number of crop/species scenarios, plus more robust, up-to-date data for setting residues per unit dose (RUD), along with revised deposition factors.

The guidance also introduces new considerations such as exposure beyond treated areas within the terrestrial area of interest (TAI), recognising that some small mammal GMS may only use the crop during its later growth stages. Additional updates include assessment of risks to benthic invertebrate-eating species, and consideration of avian migration.

Two of the most critical and interconnected changes in the revised guidance are the restricted use of the time-weighted average factor (fTWA) and the introduction of benchmark dose modelling (BMD). The default fTWA value of 0.53, previously applied for long-term exposure estimation, is now subject to restrictions. In addition, the guidance replaces the traditional no-observed-adverse-effect-level (NOAEL) approach with benchmark dose modelling at the 10% response level (BMD10), which is considered a more robust and scientifically appropriate method for setting long-term endpoints.

Further details

EFSA has developed an online tool to support the use of the new guidance. The birds and mammals risk assessment calculator is available at EFSA's website, along with detailed guidance on its use. There are also two BMD EFSA tools available, the Frequentist and Bayesian models, with the Bayesian method being recommended in the guidance to make full use of prior probabilistic distribution data. Careful consideration is required to determine which is the most appropriate for the dataset in question.

Sagentia Regulatory has carried out several assessments of compounds under the revised guidance, and our findings confirm that many of the changes make passing the Tier 1 assessment significantly more challenging. This often necessitates higher-tier risk assessments and, in some cases, the generation of additional data. In the worst-case scenario, these requirements can impact the registrability of the intended uses of the PPP.

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Flowcharts for fTWA decision making, EFSA birds and mammals guidance 2023

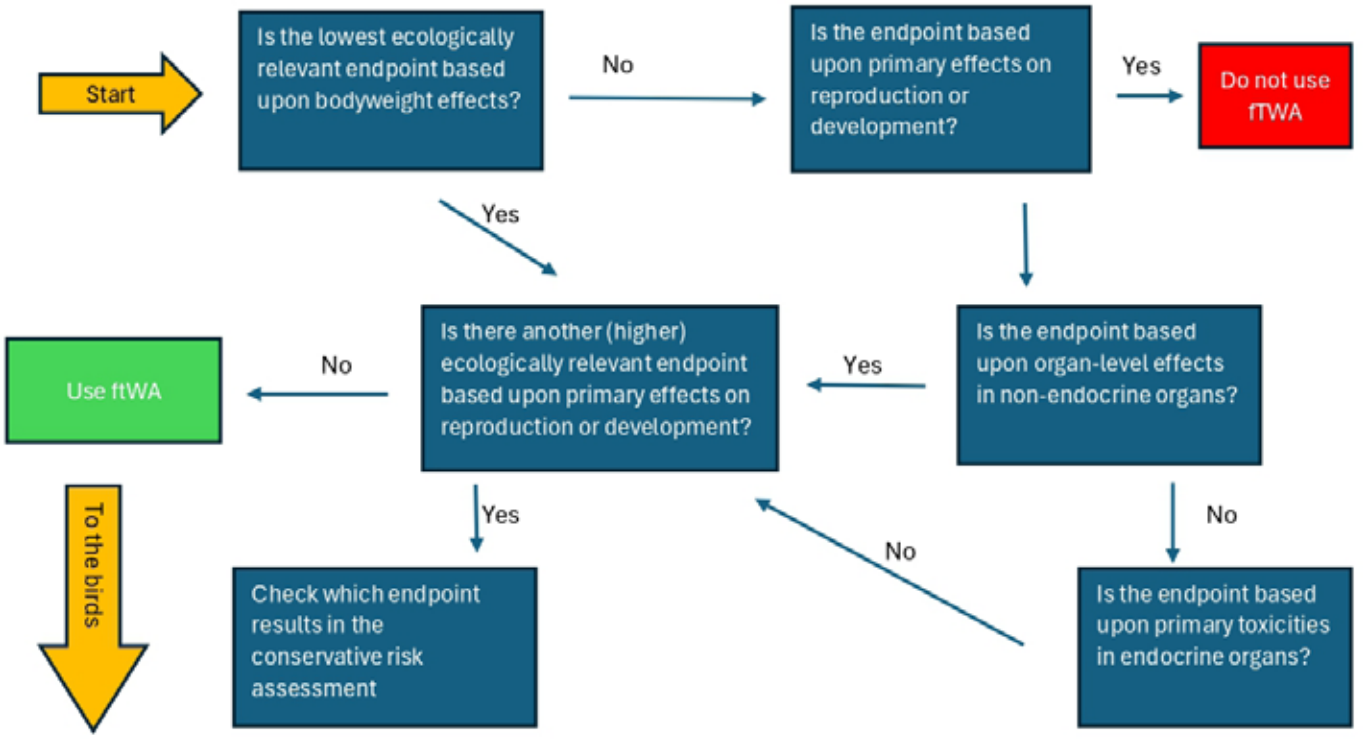
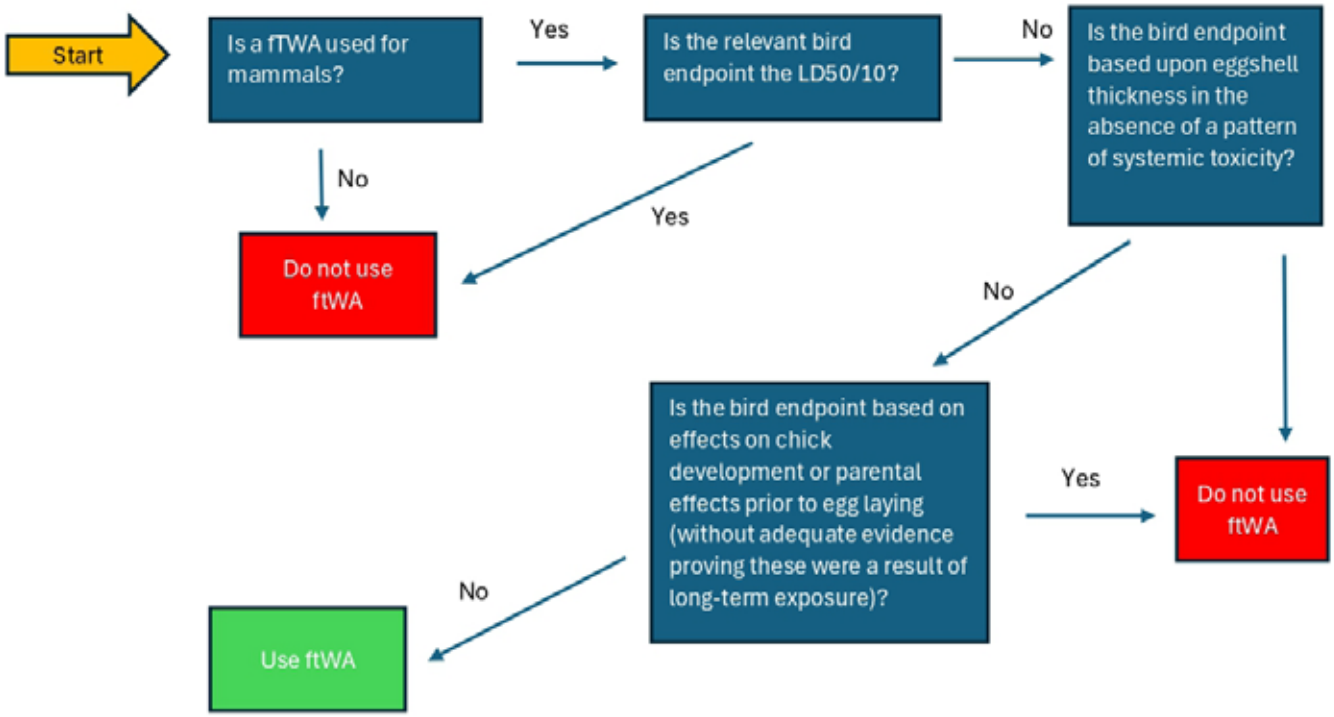


Figure 1. Flowchart for deciding if fTWA can be used in the risk assessment for mammalas.



An exception may be in the case that sufficient data on birds are available to allow the applicant to clearly justify use of the fTWA for birds. Some data may be extracted from the studies in order to support argumentation relating to time-to-effect considerations.

Figure 2. Flowchart for deciding if fTWA can be used in the risk assessment for birds.

fTWA restrictions

Under the previous guidance, a default fTWA of 0.53 could be applied to estimate long-term exposure to an active substance, representing a 21-day time-weighted average concentration in the diet based on a default half-life of ten days. Under EFSA's 2023 guidance, this approach is no longer automatically permitted; instead, an assessment is required to justify whether using an fTWA alongside the lowest ecologically relevant endpoint is appropriate (see Figures 1 and 2, adapted from the EFSA 2023 guidance document).

If an fTWA is not applicable for mammals, it is also excluded for birds. Furthermore, EFSA explicitly states that an fTWA of 0.53 cannot be used in avian long-term risk assessments where the LD50/10 (already considered conservative) applies. However, with careful evaluation of the data and good scientific justification, it is often still possible to support the use of fTWA within the risk assessment.

Toxicity endpoints

Another new requirement that can lead to more conservative Tier 1 assessments is the introduction of standard benchmark dose modelling (BMD), set at the 10% response level (BMD10). BMD is considered a more robust approach than the previously used NOAEL method, as it utilises the entire dataset across all dose levels rather than relying on a single treatment group. EFSA guidance on the BMD approach was published in 2022 (EFSA Journal 2022;20(10):7584).

Before calculating BMD10 values for reproductive risk assessments, it is essential to consider the ecological relevance of effects, in line with EFSA's detailed 2023 guidance on this matter.

Where relevant, the observed dose responses also need to be evaluated to determine whether BMD calculations are required and feasible.

This can be one of the most challenging areas of the risk assessment and can take the most time. Expert judgement is essential to ensure the most efficient approach is taken, including determining where BMD modelling is feasible and meaningful, as well as which model to use and which individual settings to apply.

Brown hare. Photo: RSPB

Zonal harmonisation

As noted above, EFSA's revised birds and mammals guidance applies to both active substance approvals and PPP authorisations. However, setting endpoints and determining the applicability of fTWA values at product level for each PPP across different zones could create inconsistencies. Current indications are that some zones or Member States may continue using EU-agreed NOAELs in risk assessments until BMD10 values are established at EU level (as outlined in the Guidance Document on Work Sharing in the Northern Zone, Version 13, 2025).

Proactive engagement with regulatory authorities and staying informed on EU-level discussions can provide valuable insight into evolving expectations and help mitigate potential challenges.

Integrated expertise for a changing regulatory landscape

In summary, EFSA's revised bird and mammal guidance represents a significant shift in risk assessment methodology, introducing more stringent and scientifically robust approaches that will challenge traditional practices. Companies should not underestimate the complexity of these changes – particularly the implications of BMD modelling, restricted fTWA use, and the expanded scope of exposure scenarios.

The complexity and interconnected nature of these changes mean that companies will need a multidisciplinary approach – combining toxicology, ecotoxicology and statistical expertise – to navigate the revised EFSA guidance effectively. Early engagement and proactive planning are key to maintaining product registrability and avoiding costly delays.

References

https://doi.org/10.2903/j.efsa.2022.7584

https://doi.org/10.2903/j.efsa.2023.7790

https://eng.mst.dk/media/ae0itvod/northern-zone-guidance-document-ver-13-june-2025.pdf

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With more than 25 years' experience in ecotoxicology, Jennifer has a deep understanding of the scientific and regulatory factors that must be considered when placing plant protection products on the EU market. As Principal Ecotoxicology Consultant at Sagentia Regulatory (formerly TSG Consulting), she supports clients with data gap analysis, risk assessment, and dossier development, in alignment with guidance from relevant authorities such as EFSA. Her expertise spans birds and mammals risk assessment, including higher-tier assessments, and regulatory strategy.