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INSIGHT

Navigating the impact of EFSA's revised birds and mammals guidance

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With the new guidance in place, fewer compounds will successfully pass Tier 1 assessments

The European Food Safety Authority (EFSA) has revised its guidance document on the risk assessment for birds and mammals. This update introduces significant changes that will affect pesticide companies operating within the EU. Understanding these changes and their implications is crucial for companies to adapt and thrive in the evolving regulatory landscape.

The risks to birds and mammals from potential exposure to plant protection products (PPPs) are currently assessed in the EU using the EFSA guidance on risk assessment for birds and mammals from 2009 (EFSA Journal 2009; 7(12):1438).

Given the age of the guidance, the European Commission mandated EFSA to revisit and revise it according to current scientific knowledge and understanding.

The revised EFSA guidance document on the risk assessment for birds and mammals (EFSA Journal 2023;21(2):7790) was endorsed at the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) meeting in October 2024.

SCoPAFF agreed that the revised Guidance Document on Risk Assessment for Birds and Mammals should apply to dossiers submitted from October 2025 onwards, in the context of (renewal of) approval of active substances under Regulation (EC) No. 1107/2009 and in the context of (renewal of) authorisation of plant protection products under Regulation (EC) No. 1107/2009.

The Applicant may choose to apply the revised guidance document earlier. If so, this decision must be specified in the dossier and will be irrevocable.

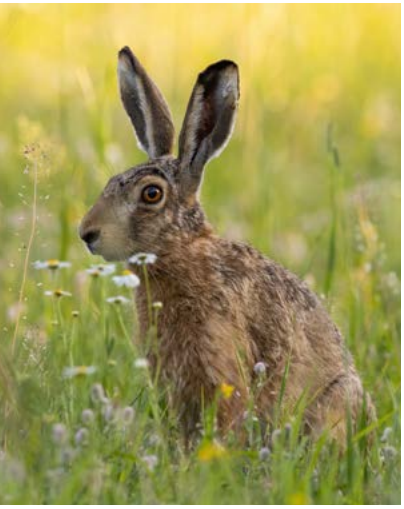
TSG has conducted several reviews of compounds under the revised guidance in preparation for the upcoming implementation. Our findings confirm that many of the changes make it more challenging to pass the Tier 1 assessment. This could potentially necessitate higher tier risk assessments and/or additional data, and in the worst-case scenario, impact the registrability of the intended uses of the plant protection product (PPP).

What can PPP companies do to prepare?

Our advice is to be proactive, conducting a systematic review of active substances and products across the portfolio. The first step is to identify which PPPs require renewal of authorisation. Once identified, prioritise those containing active substances that are close to the margin of failure based on EFSA (2009) guidance for compound analysis aligned with the new requirements. It is crucial to work ahead to allow sufficient time for preliminary assessments and, if necessary, generation of further studies to support higher tier risk assessments.

The revised guidance introduces numerous changes, including (but not limited to) indicator model species, generic model species, residues per unit dose, deposition factors, the introduction of benthic invertebrate-eating species, and the consideration of exposure outside the treated area but within the terrestrial area of interest.

Based on our evaluation of the revised guidance, two connected and critical areas are: restricted use of the time weighted average factor (fTWA) and changes to the toxicity endpoints used in long-term assessments.



fTWA restrictions

Under the previous guidance, a default fTWA of 0.53 could be applied when determining the long-term exposure to an active substance. This equates to an estimation of the 21-day TWA concentration in the diet, assuming a default half-life of ten days. EFSA (2023) does not always allow this option, instead requiring an assessment to determine whether it is appropriate to use an fTWA in conjunction with the lowest ecologically relevant endpoint.

The initial focus of the fTWA change is the mammalian dataset. If the fTWA is not allowable for mammals, it is also precluded for birds. Additionally, EFSA (2023) guidance explicitly states that an fTWA 0.53 cannot be used in avian long-term risk assessments where the LD50/10 endpoint applies, which is already a conservative approach.

However, based on TSG's experience, with careful consideration of the data and detailed justification, it is not uncommon to be able to support the use of the fTWA in the risk assessment.

Toxicity endpoints

Another new requirement that may result in more conservative Tier 1 assessments is the introduction of standard benchmark dose modelling (BMD), set at the 10 percent level (BMD_{10}). BMD is considered a more appropriate method than the previously used no-observed adverse-effect-level (NOAEL) approach, as it utilises the entire dataset across the dose levels used in the study rather than just one treatment group. EFSA guidance on the use of the BMD approach was published in 2022 (EFSA Journal 2022;20(10):7584).

Before initiating the calculation of BMD_{10} values for reproductive risk assessments, it is essential to consider the ecological relevance of effects, following the detailed guidance provided in EFSA (2023). 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.

A proactive response will pay off

As discussed, the developments surrounding fTWA and BMD will collectively result in fewer compounds passing Tier 1 assessments under the revised EFSA guidance.

Understanding which compounds are likely to fail Tier 1 risk assessments is vital for informing and shaping regulatory strategy. Higher tier assessments may necessitate evaluating the relevance and reliability of existing data against revised criteria. Additionally, it may be necessary to gather new data that accurately represent real species and environments. Since new studies may be needed to generate these data, early planning and preparation are essential, especially where field trials subject to seasonal variations are required.

EFSA has developed an online tool to support the transition to the new guidance. A beta version of 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.

At TSG, we offer streamlined preliminary assessments, as well as full assessments, under the revised guidance on individual active substances, products, or entire product portfolios. We also conduct more detailed compound analysis when required and can advise on next steps if additional data are likely to be needed. If you're looking for expert support and scientific insights on how to respond to EFSA (2023) birds and mammals guidance, please get in touch at info@tsgconsulting.com.

About TSG Consulting

TSG Consulting, part of Sagentia Regulatory, provides companies with high quality regulatory and scientific consulting services. We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, pet food, and animal feed. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry. This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance. TSG Consulting has offices in Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

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For further information visit us at:
www.tsgconsulting.com or
email info@tsgconsulting.com

TSG Consulting
Concordia House
St James Business Park
Grimbald Crag Court
Knaresborough
North Yorkshire
HG5 8QB
UK

TSG Consulting
1150 18th St NW
Suite 475
Washington DC
20036
USA

tsg