

Key Outcomes of a Virtual Workshop on Avian Higher Tier Studies under the new EFSA Birds and Mammals Guidance Document

MEET US AT BOOTH 109!

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INTRODUCTION

The revised EFSA guidance document for the risk assessment for birds and mammals (GD) [1] provides guidance for the evaluation of plant protection products and their active substances under Regulation (EC) 1107/2009. The new guidance considers new regulatory frameworks and scientific developments, as well as the possible harmonisation of higher tier methodologies.

However, the practical implementation of the new requirements for higher tier refinement options introduced by the revised EFSA birds and mammals guidance document [1] remains vague in some particular aspects. In order to discuss existing uncertainties and to identify feasible solutions and acceptable ways for conducting higher tier field studies, a series of virtual workshops on higher tier refinement options for the EU birds and mammals risk assessment was initiated by CropLife Europe.

IDENTIFICATION OF STUDY AREAS FOR BIRD FOCAL SPECIES STUDIES

Instead of focussing on prevalence and abundance, the revised GD [1] highlights the significance of identifying the most vulnerable species per feeding guild as relevant focal species (FS). A stepwise approach is proposed (see talk [2]) that combines occurrence of species and crop cultivation.

- general agreement: method integrates crop and species occurrence, aligning with ERA
- open questions/uncertainties regarding
 - data sources
 - acceptance of databases by authorities
 - consideration of long-term changes (e.g., climate change) of species and crop occurrence
 - wordings such as “regionally specific but relevant species *may* have to be considered”

Workshop

- virtual workshop with three presentations, breakout groups and plenary sessions
- 93 participants from authorities, academia, CROs and industry (Figure 1)
- workshop format was seen as very useful and a good opportunity for constructive exchange between stakeholders
- GD has a number of aspects that need further clarification or could be misinterpreted

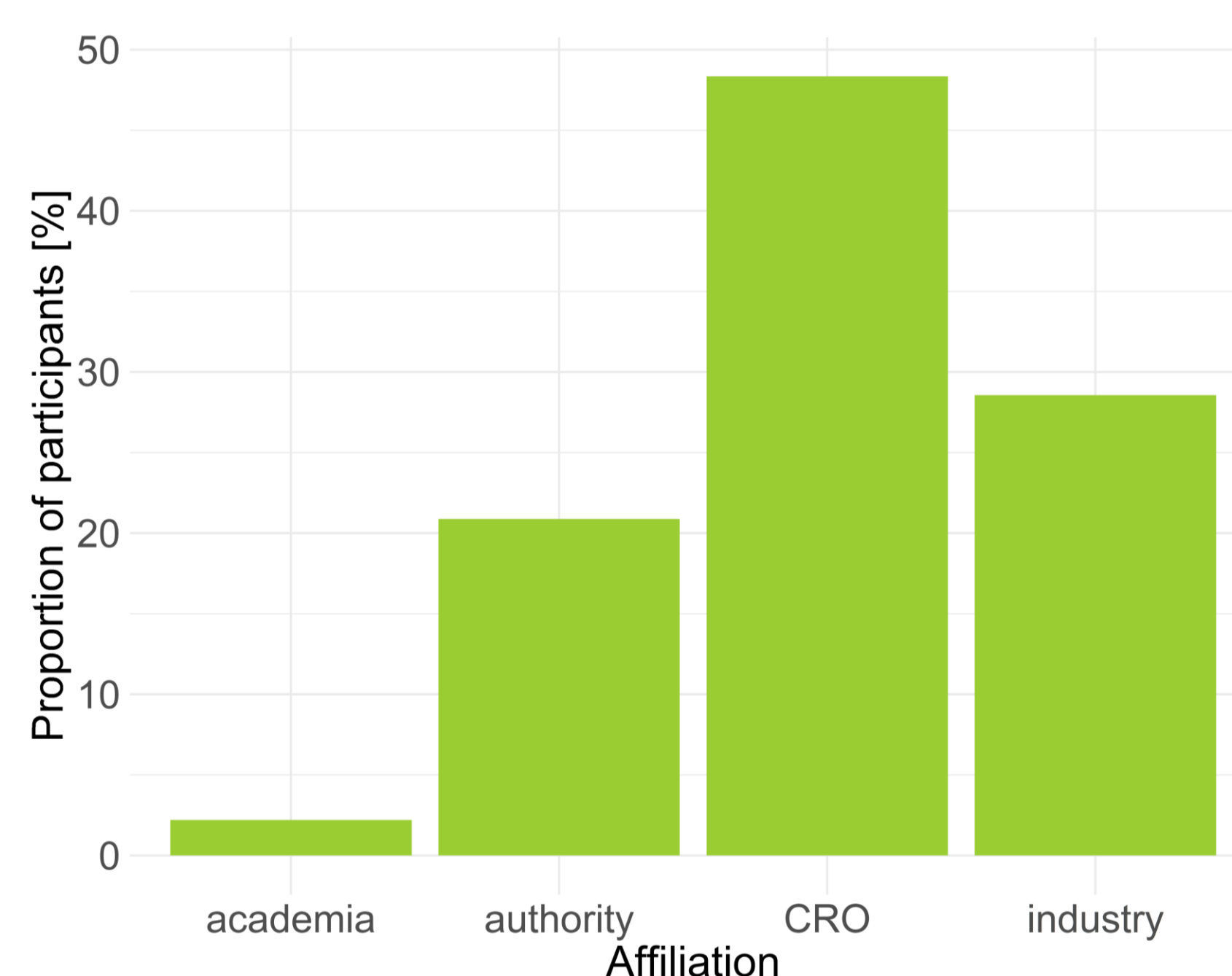


Figure 1: Affiliation of workshop participants

FOCAL SPECIES FIELD STUDY – FACTORS TO CONSIDER

The revised GD [1] requires field studies to target and cover realistic worst cases regarding vulnerability and exposure of potential FS. However, clear assessment methodologies regarding important factors, such as agricultural practice or food availability, are missing.

- uncertainty regarding which agricultural practices are considered 'worst case' (may vary between species)
- assessment of food abundance not mandatory according to the guidance, depends on study purpose: expendable as occurrence of birds indicates food availability, but useful for future proofing
- consideration of additional key factors such as information on off-crop areas, species survey methodologies, seasonal influences on bird behaviour, or weather conditions
- consensus that transparent agreements on field methodologies and assessment approaches are necessary to avoid inconsistencies and variations in the interpretation of studies

BIRD FOCAL SPECIES SELECTION – AN APPROACH TO REFINE THE VULNERABILITY IN BIRD FOCAL SPECIES SELECTION

The revised GD [1] emphasizes vulnerability as important criterion for FS selection, but detailed guidance on the assessment of vulnerability is missing. An approach is suggested (see also poster [3]) that uses the daily dietary dose (DDD), surrogating the PT in the formula with the frequency of occurrence in survey (FO_{survey}) calculated from FS study data.

- general consensus that vulnerability can be approximated by species-specific exposure, i.e. DDD
- life history traits should be considered in tier 4
- assessment of the species coverage by DDD using FO_{survey} is identified as potentially useful approach to exclude less relevant species
- uncertainties regarding
 - selection process for FS: expert judgement (e.g. inclusion of ecological trait, threshold definition) leaves room for interpretation
 - preferences of individual member states for particular species of concern

Conclusion

- There are uncertainties surrounding the practical implementation of new higher tier refinement options introduced by the revised EFSA Birds and Mammals guidance.
- The virtual workshop was a successful way to discuss innovative approaches and address the new requirements and associated uncertainties, and to build consensus on approaches that are feasible, acceptable and transparent to all stakeholders.
- Future virtual workshops will target further topics on the new requirements for higher tier studies introduced by the new EFSA birds and mammals guidance.
- A number of topics for future workshops were identified, with Benchmark Dose Modelling and the use of the f_{twa} ranking highest.

REFERENCES

- [1] EFSA 2023. Risk Assessment for Birds and Mammals. EFSA Journal 21(2): 7790. doi: 10.2903/j.efsa.2023.7790.
- [2] Hotopp I, Gießing B, Russ A, Wolf C, Schad T, Ebeling M. 2024. Think twice before you chose your study site – Identification of Focal Species Study Areas Under the Revised Birds and Mammals Guidance Document. Talk at SETAC Seville.
- [3] Hotopp I, Russ A, Gießing B, Wolf C, Kragten S, Weyers A, Fan M, Sprenger D. 2024. A Proposal on How to Consider 'Vulnerable Species' in bird Focal Species Selection. Poster at SETAC Seville.



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