Virtual workshop series on the new EFSA birds and mammals guidance document

1ˢᵗ Topic: Focal species derivation for birds

March 14, 2024 | 9:00 – 15:00 CET

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(Luscinia svecica, breeding season)

Workshop-Minutes

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Introduction

The revised EFSA guidance document for the risk assessment for birds and mammals was published in spring 2023. It includes new requirements for higher tier studies but remains vague in the practical implementation of some aspects. In order to discuss acceptable approaches to conduct higher tier studies also in the future, a series of virtual workshops on higher tier refinement options for birds and mammals in the EU was initiated by CropLife Europe.

The first workshop in this series on avian higher tier studies was organized by tier3 solutions and took place on 14th March 2024. Stakeholders from industry, CROs, regulators and academia were invited to join in an exchange at eye level. The focus of the workshop was on jointly discussing possible solutions for addressing the requirements set by the EFSA birds and mammals guidance document on the risk assessment for birds and mammals (2023) in order to reach a consensus about a concept that is practicable and acceptable for all contributors.

Therefore, practitioners in the field presented short plenary talks that outlined the current status of higher tier refinement options and innovative approaches that would meet the new B&M guidance expectations. The talks gave an initiation for discussion of scientifically sound and yet practical ways of conducting and evaluating higher tier studies. Afterwards, participants exchanged ideas in sub-groups. The results of these discussions were presented and discussed subsequently in the plenary. In total, 93 participants joined the virtual workshop on March 14th 2024 (Figure 1).
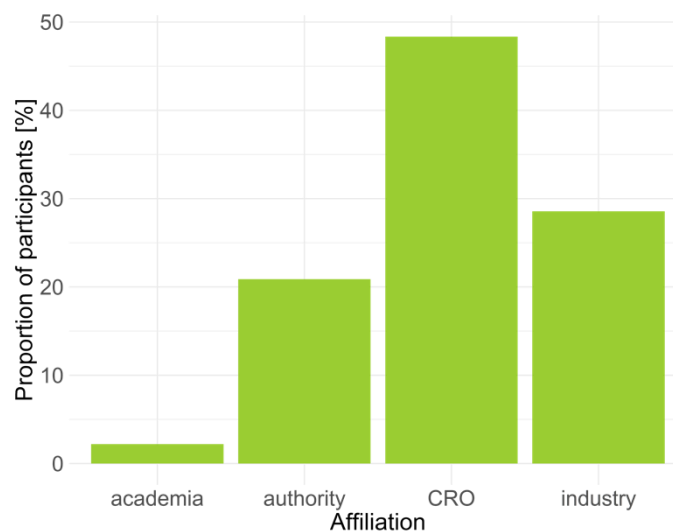

Figure 1 Participant affiliation of the virtual workshop.

Session 1: Identification of study areas for bird focal species studies

The recently revised EFSA guidance document for birds and mammals highlights the need to put more effort in the identification of the most vulnerable species per feeding guild as the most appropriate focal species (FS). It is now emphasised that not only prevalent and abundant species with a higher frequency of occurrence (FO) are to be considered, but also rare and/or more locally distributed species. A low abundance should not generally eliminate a species from consideration.

> *"[…] regionally specific but <u>relevant species</u> may have to be considered [...]."*

A vulnerable species which is infrequently observed but nevertheless clearly present may be considered a more appropriate FS for the risk assessment, and more protective of similar species, than a less vulnerable species with a higher occurrence. Hence, already the selection of the study area to conduct a focal species study is crucial for including all relevant species.

The presented approach suggests to create a list of potentially relevant species by excluding species from a comprehensive list that reliably are not relevant in the crop of interest at the specified time of the year. Then occurrence of the potentially relevant species and occurrence of the crop of interest are combined and potential study regions are selected (see presentation '1 - Selection of areas for focal species studies – w notes.pdf').

The approach was found to be promising. Participants were informed that the aim of the guidance is not to have a single FS study but to have an iterative process depending on the following step. However, it was found by the participants that this may not be feasible in practice, as an iterative process would take too much time.
For the northern regulatory zone, a focal species list depending on crop, BBCH and feeding guild exists for the old guidance. It will have to be adapted for the new guidance.

Break out group discussions

In general, the presented method was regarded as a formalized, structured approach that combines the occurrence of crop and species, and was found to be consistent with other areas of environmental risk assessment.

In the past, site selection was almost entirely based on the occurrence of the crop. Most participants agreed that overlaying the crop with bird diversity/occurrence data is an improvement. Participants also acknowledged that a FS field study cannot cover all imaginable scenarios. However, a well-documented process, like the one proposed, for site selection based on crop occurrence and also avian biodiversity would be useful.

Literature data can be used but its relevance has to be checked carefully. Additional literature data and smaller scale studies could be used to cover regionally specific species.
It was found that ideally a list of focal species per crop, BBCH class and feeding guild is compiled by the authorities for each regulatory zone. However, participants realized that this might be a difficult task because of the diversity in the central and the southern zone. It can be an option for individual member states.

As the presented approach requires a lot of effort, prior knowledge about the acceptance by the authorities is necessary and harmonization would be needed. Relevant, accessible and accepted data sources would have to be agreed upon and kept up to date.

Participants were sceptical about the availability of data, especially the occurrence of bird species in the crop, and the acceptance of databases by the authorities. A thorough evaluation of the underlying data might be necessary. Due to the dynamic circumstances, the acceptance of an analysis might be revoked after some time.

It was suggested to include the vulnerability, e.g. in form of body weight, in the selection of study areas. Concern was raised about what to do if a species, which should be in the selected according to the list, cannot be found. The differentiation between farmland areas and other habitats as well as short-term local changes in crop occurrence are not relevant here as a 50 x 50 km² grid is used, which can include multiple habitats and landscape characteristics in one cell. The occurrence of a species indicates suitable habitat characteristics within the region and the occurrence of the crop is regarded on a wider spatial resolution than at field level. However long term changes due to e.g. climate change need to be considered for species as well as crop occurrence. Landscape structure and management structures such as field sizes will have to be considered in the next step when selecting the study fields. As a key parameter, besides species and crop occurrence, the agricultural practise (AP) was identified. Databases with this information exist and could possibly be used. Due to changing environments, the definition of other key parameters was found to be difficult. The diversity of the landscape has a significant impact on species numbers and abundance, but may result in lower amounts of certain crops in the landscape. The real-time identification of crops from satellite images is a useful tool that can be incorporated into this approach. Country specific needs could be considered by suitable bridging statements or in dialog with the respective regulatory authorities.

The discussion about using random study regions as an alternative to the presented approach was inconclusive. A random selection was determined to be less robust and rare species might be missed. Other participants were of the opinion that a random selection can work and some participants found that there are more approaches between the two extremes that could work. A comparison between the two approaches was suggested to find out differences.

The wording "regionally specific but relevant species may have to be considered" in the guidance was discussed with special focus on the word "may". It was found that this is a factor that adds to the uncertainty and makes it more difficult to plan and conduct a study and a clarification would be useful. It was suggested that in the refinement process, regionally specific species might become important at a later stage as it is a stepwise approach. Another interpretation was the coverage of similar species from an ecological point of view. An open question was if a country would accept being covered by other countries in the zone and not by studies conducted in the respective country, although they should accept that according to the guidance.

The concept of starting with a long list of species and then reducing this list by excluding species was discussed. It was agreed that exclusion need good arguments but that this concept might be better than adding species to a short list of species known to occur in the crop from literature. Adding species instead of excluding them needs expert judgment from the beginning whereas excluding starts with reasons that are widely agreed upon. The concern that the careful exclusion of species might lead to a long list with many species was countered with the argument that this step is not about selecting the species but of finding areas where they occur. Excluding species not occurring in the crop was found to be a difficult step as a lot of expert knowledge might be needed. Literature of bird sighting might be used and in some cases, species might be covered by similar species that are known to occur in the crop. However, the resulting list of potentially relevant species should be a conservative list and the switch of feeding guilds of a species throughout the year should be considered.

Session 2: Focal Species Field Study – Factors to consider

The instructions in the revised EFSA guidance document for birds and mammals regarding the selection of focal species aim to avoid missing a realistic worst case in terms of vulnerability and exposure of potential focal species. Hence, the requirements should be sufficiently addressed in a field study to achieve and descriptively show that the realistic worst case is targeted and covered by the study. While these requirements for higher tier studies have been included in the guidance document, a clear methodology was not proposed, regarding the assessment of e.g. agricultural practice, food availability and focal species assessments. The objective would be to agree early on field methodologies to avoid inconsistent and variable interpretation of methodologies and results (see presentation '2 - Factors to consider for FS study - w notes.pdf ').

Break out group discussions

Regarding the **food abundance**, it was clarified by a member of the expert group who had developed the new guidance document that, for focal species studies, these measurements are not mandatory according to the guidance, it is only a recommendation[1] to assess the food abundance in the study so that this information can be used when bridging is necessary, for example between different pesticide types (e.g. herbicide ←→ insecticide). Hence, collecting the information about food abundance also depends on the regulatory purpose of the study in the future. The assessment of the food availability will rather be a proof for future usage instead as for the current study.

It became obvious in the discussion that there is a large uncertainty about the assessment of food abundance and availability. In general it can be stated that if the (expected) birds are observed, the food availability is sufficient and an assessment not essential. The problem arises when there are no birds, because then their absence needs to be verified. One potential reason might be that alternative food sources in the surrounding may prevent birds from foraging on the field.

Furthermore, another uncertainty was that it cannot be known in advance, whether any member state ask for food abundance data despite it is only a recommendation in the guidance. Hence, the conclusion was that the assessment of food abundance should be included to be on the safe side, although it will increase the extend (costs) of the study. To facilitate the assessment, one could differentiate between indirect measures, (i.e. the presence of birds justifies food abundance is enough to support occurrence of birds) vs. directly (count of seeds, plants, …) measuring the food abundance. Due to the uncertainty about the what and how of food availability, substantial effort would be required to investigate it comprehensively. This effort might be reduced by focusing on a certain feeding guild.

However, the questions arose, what the reference of food availability is and to what should it be compared? What will be a representative benchmark? A suggestion was made to use reference fields in the same study area (where focus is not bird observations) to show that the study fields are indeed typical/representative. Another suggestion was to use the food abundance as a backward verification: Where all expected species observed? If not, look at the food abundance for that feeding guild or species. If the food is absent as well, take another backwards step and look at the agricultural practice.

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[1] "The landscape characteristics must be well-described, particularly considering their relevance to the species under consideration (e.g. depending on the study objective, the following may be reported: weed/insect/seed abundance, presence of water bodies compensatory areas, hedgerows, roosting sites, size and composition of field margin, etc.). This can be supported by e.g. habitat mapping, photographs, GIS data, etc." (6.5.2.2. Description of agricultural practices, page 78 of EFSA, 2023).

In terms of the **agricultural practice**, there was a large uncertainty about what can be considered the (realistic) worst case. Especially, since the worst case might be different for different species. Even simple aspects (e.g. use of fertilizers) can influence the presence of some species but not others, because the worst case depends on the feeding guild of a particular species. Therefore, it should be addressed in a subsequent refinement study that focuses on a single species as it is not possible to define a worst case for all species in one scenario.

Another suggestion was to focus on the most common/representative agricultural practice, but this may change over time and might be challenged, also. Nevertheless, the agricultural practice should already be part of the considerations during site selection.

Agricultural practice and food abundance were stated to be heavily intertwined in an area. Therefore, if there are uncertainties about agricultural practice, one could do a pre-assessment of food abundance to verify whether that was representative and link the conclusions back to agricultural practice. Also, if agricultural practice is representative, food abundance is a result of that and should not need further consideration.

Regarding the question which **information is needed for the off-crop area**, it was agreed that different habitat types in the surrounding of the study fields are necessary to cover all possibly occurring species, here literature and historical data might be useful. In order to demonstrate that all habitats are covered, a comprehensive reporting is necessary, though it is unclear to which extent and scale (immediate surrounding / adjacent fields / entire landscape). As an answer to this, it was suggested to use a zonal approach: using a high spatial resolution for the inner study field zone and a less detailed resolution on the outer zone. Here, the question was raised whether this approach is also useful for the temporal extent.

In general, factors that affect the behavior/vulnerability of the species should be included to verify the representativeness of the off-crop area. Also, the recent or past use of pesticides in the surrounding might be a confounding factor and other factors that limit the bird presence apart from the food availability, e.g. whether the off-crop area provides suitable nesting sites. This may also include landscape structures in the wider surroundings, water bodies or proximity to urban areas or roads, that may cause disturbance. All these factors might depend on the species, the time of year and the crop. Here, the problem was raised that the off-crop variability can be huge. This will increase the number of fields to be observed or if reduced, it will increase room for critics.

Here, also the Critical Appraisal Tool (CAT) was mentioned. The CAT uses unspecified requirements ("adequate", "appropriate") that complicates the evaluation.

When planning a field study, there are additional **key parameters** that should be considered. It is still suggested to use 20 study fields, but the number of surveys should be sufficiently high to allow well-founded calculations and statements. In this regard, point counts were mentioned as an additional method for focal species studies apart from scan sampling, transect counts and trapping. This method can also be used in- and off-crop area but getting quantitative results was questioned. In general, the choice of method should be flexible depending on the research question, since all methods have advantages and disadvantages.

The behavior of the birds also depends on the time of year, e.g. they are more territorial during breeding season, can have enormous feeding bouts during migration, show different flocking or feeding behavior. This has to be taken into account. Especially migratory birds should not be overlooked and may be more difficult to find in a certain number of fields. This should be considered in study area selection, because a combination of survey methods might be a useful approach to avoid this. New methods like sound recordings or environmental DNA might be promising as well.

In terms of weather conditions it was suggested to conduct the surveys during a study as far as possible under similar conditions in order to enable comparability.

Session 3: Bird Focal Species Selection – An approach to refine the vulnerability in bird focal species selection

The revised EFSA guidance document for birds and mammals emphasises vulnerability as criterion rather than prevalence for FS selection. Weyers et al. (2022)[2] suggest to rank FS candidates according to their expected magnitude of exposure by calculating a species-specific daily dietary dose (DDD). With this, species with a potentially high exposure would be ranked as potentially more vulnerable and are identified as candidates for focal species. The DDD is calculated using – among others – the estimated 'proportion of diet an individual obtains from the (potentially) treated crop' (PT). A real PT is assessed through a radio-tracking field study, but not for all species such field data are available. Here, a proposal was presented on how to obtain a PT surrogate in order to rank potential FS species according to their vulnerability (see presentation '3 - Bird focal species selection - w notes.pdf').

Due to the demanding nature of the third presentation, participants were hesitating to comment. For the example on how to come up with a FS species, it was asked how the result would differ, if only the body weight was considered. As the example uses only birds of the same feeding guild, the result would have been the same as for the DDD with PT set to one. The influence of FO_{survey} on the ranking can be quite large. A question was asked if in the same example the Chaffinch was regarded as protective for the Goldfinch as the Goldfinch has a higher – the highest – DDD when the PT is set to one. This was answered positively as the expected usage deduced from FO_{survey} of the crop by the Chaffinch is much higher than the one from the Goldfinch and thus the Chaffinch has a much higher DDD_{survey}.

Break out room discussion

It was discussed if FO_{field} really is 'out of the game' or if it should be an option for the future, especially depending on the still available data/studies. The frequency of occurrence does not automatically reflect the use of the habitat correctly; information from literature might be useful (even prior to the definition of FS) and PT-studies are still important. Furthermore, it was remarked that behaviour information collected during the FS study could also be useful.

The inclusion of ecological traits in the selection process need expert judgement, which might be biased. Judgement may be based on literature and review steps should be transparent. Existing and widely accepted data on ecological traits are to be preferred here.

The presented approach has no 'cut-off-criteria' incorporated. Thus, it is an open question which species should be considered as FS.

It was found to be of interest how DDD_{survey} behaves as compared to the 'real' DDD.

It was agreed in general that the presented approach would not lead to substantially different species selection than the old approach, but possibly a few more species that need to be considered in a PT study. These additional species would be species that are rather rare but use the crop frequently. For crops with less data, a limited impact was expected; for crops already covered well, no differences in the selected species were assumed.

There could be differences due to different risk assessors as there is always room for discussion/options for the selection. When considering not only the most vulnerable but also most rare species, a zonal regulatory approach was found to not always make sense, as a species might be only a concern for one country but not for the other. For a general approach, the common species might make more sense than rare species as rare species always require rather a local approach. The

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[2] Weyers A, Sprenger D & Kragten S (2022) Focus matters – Bid focal species for higher tier risk assessment. Poster at SETAC Copenhagen

spatial aspect also emerges in differences in product registration (national level) versus active substance registration (zones).

It was suggested to confirm the presented approach by conducting a study with using it and compare the results with old studies. If results are similar, the presented approach could be used for the old data.

The need of an extensive FS study campaign was formulated to avoid missing any species. Alternatively, experts could be consulted on which species might be missed in existing studies. Missing species then could be added, if necessary, by smaller and focussed field studies.

Leaving the 20% FO_{field} criterion behind was seen to aim to protect populations, not the most frequent species and the step to using vulnerability instead was found to be sensible for a protective risk assessment. There was never a scientific reason behind the 20% threshold. However, existing study data should not be disregarded. In some cases, this approach could be used to make final decisions. Some participants also found that prevalence of species is still important.

As critical factors for the selection of FS ecological and life history traits, endangerment/rarity, exposure, timing if applicable and vulnerability were considered. However, there could be preferences of member states that have particular species of concern. It was found that lines or thresholds need to be discussed and defined. Furthermore, life history traits can be incorporated in tier 4.

A ranking system was found to be necessary to filter out species with a presumed high risk, although thresholds need expert judgement. Other criteria than exposure were regarded not necessarily as relevant. Uncertainties should be covered by safety factors. Migration/ overwintering should be considered in relevant cases. The pest status of bird species in a particular region and crop might be important, also game species and hunting activities. An alternative could be the IUCN status or to use literature to identify vulnerable species.

A more comprehensive ranking approach including life history traits was suggested that is used always or under certain conditions. It was proposed to take life history traits into account in the tier 3 (PT/PD) risk assessment only when deviating from the worst case. At tier 4, life history traits are important.

Topics for the next virtual workshop(s)

At the end of the workshop a polling was performed among the participants about their ideas and proposals for the next workshop(s). The following topics received more than one vote:
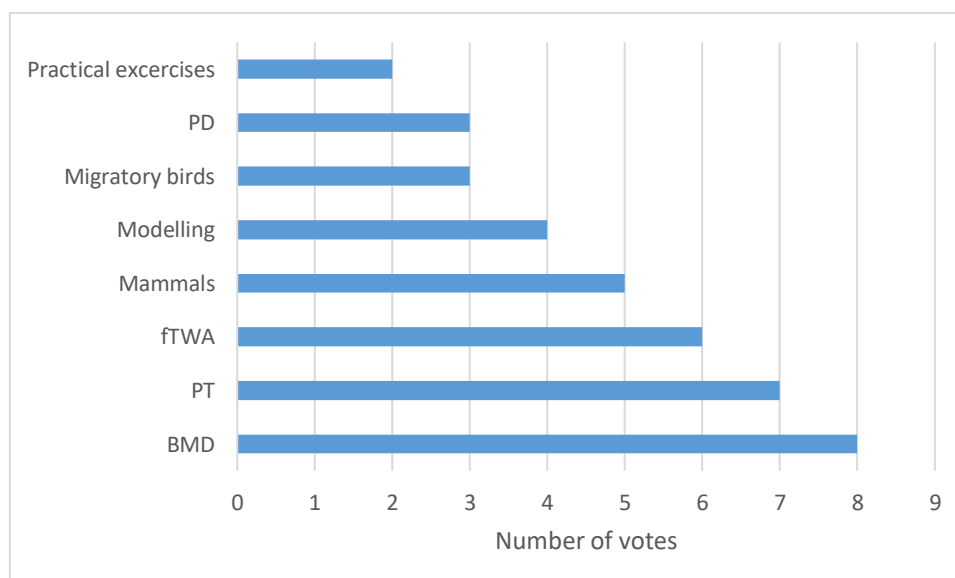
Further topics mentioned were:
- Biopesticides
- Endpoint selection
- Overspraying design for aquatic testing
- Pooling data from existing PT studies
- Proposal of a cut-off criteria for FS after gaining experience with the new GD
- Seed treatment RA
- Spot applications
- Unstable substances - avoiding geomean concentrations when degradation is well supported with data
- Effect studies

Presentations

The three presentations are provided as separate pdf files:
- 1 - Selection of areas for focal species studies – w notes.pdf
- 2 - Factors to consider for FS study - w notes.pdf
- 3 - Bird focal species selection - w notes.pdf