DERIVING ECORELEVANT ENDPOINTS FOR WILD MAMMALS UNDER DRAFT NEW BIRD AND MAMMAL GUIDANCE (EFSA 2021)

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Background: The potential risks to wild mammals must be assessed for pesticide authorisations in the EU. The current bird and mammal guidance (EFSA 2009) theoretically allows the derivation of an 'ecologically relevant' wild mammal toxicity endpoint, taking into account only those effects relevant for wild mammal populations. In September 2021, EFSA released a draft new bird and mammal guidance, which includes recommendations for the derivation of ecorelevant endpoints for wild mammals. Here we highlight some questions that we have (shown in *italics*) on the draft new guidance (EFSA 2021).

Which studies to use?

- More data are available for mammals than other vertebrates (birds, fish) due to human health risk assessment – both in terms of number of studies and test durations
- Wild mammals and birds are assessed under the same framework but have different sized datasets
- Leads to ↑ level of protection for mammals → *could this be reflected in an assessment factor <5 in wild mammal reproductive risk assessments, to reflect the reduced level of uncertainty?*
- *Could we focus on the most relevant, multigeneration study? Could we use a one-generation study (EOGRTS) to match the data package for other vertebrates (birds, fish)?*

Species sensitivity

- There can be differences in lagomorph and rodent sensitivity to toxicant exposure due to the mode of action and/or animal physiology
- *Could we select the endpoint on the basis of the species most relevant to the risk assessment scenario e.g. use rodent endpoint for seed-eating mammal scenario?*

Types of effect

- Protection goal of reproductive risk assessment for wild mammals is for there to be 'no long-term repercussions for abundance and diversity'
- *Should we therefore focus on effects that can affect the protection goal → reproductive success and offspring viability?*
- Guidance clarifies that body weight is more relevant than body weight gain; *but body weight effects over what time scale?*
- Guidance clarifies that we can distinguish between body weight effects from reduced palatability versus toxic effect

Magnitude of effect

- >10% effect is considered relevant in the draft guidance document…*why? What evidence?*
- *10% of what? Occurrence? Increase/decrease?*
- *Feasibility of detecting 10% behavioural changes?*
- *All effects considered equal?*
- *Human detection of effects vs population relevance?*
- *Sufficient statistical power to use lower confidence limit of benchmark dose (BMDL)?*

CONCLUSIONS & RECOMMENDATIONS

- Increased guidance in the derivation of ecorelevant endpoints for wild mammals is welcome, as this **encourages consistency** between regulatory authorities and between active substances
- The **nuances of the recommendations in EFSA 2021 require further consideration** to ensure we are not over or under protecting wild mammals due to the assumptions being made or the data being used
- More **collaboration between toxicologists and ecotoxicologists** is required, both during dossier preparation and during dossier evaluation
- Need to keep in mind what the effects mean for wild mammal **populations**, how studies and effects are **interlinked**, and which studies are most **relevant for each effect type**

References
European Food Safety Authority (EFSA). 2009. Guidance document on risk assessment for birds and mammals on request from EFSA. EFSA Journal 7:1438.
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