The new draft guidance for birds and mammals from the perspective of practitioners

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2 tier3 solutions

1 CEA CAMBRIDGE ENVIRONMENTAL ASSESSMENTS

Introduction

- Risk to B&M from PPPs currently assessed according to EFSA GD (2009)[1]
- Tiered approach: Screening → Higher tier refinements
- New draft update to the GD released for public commenting (2021)[2]. Includes: new data, clarifications on technical points, technical meeting decisions etc.

[1][EFSA] European Food Safety Authority. 2009. Guidance Document on Risk Assessment for Birds & Mammals. EFSA J 7:1438.

[2][EFSA] European Food Safety Authority. 2021. Risk Assessment for Birds and mammals. DRAFT Guidance Document.

This presentation

- Part 1: CEA presents the risk assessor's view of changes in draft GD
- Basis, practicality, realism, and potential impact on risk assessment
- Part 2: tier3 presents the view of CRO on new requirements for higher tier studies
- Opinions, practicality, and proposals

CEA: risk assessor's view

- GD should be updated with developing science
- When presented with uncertainty in regulatory science, we have two options:
  - Assume that current assessment protective of risk until proven otherwise, or we have technology to investigate/address risk, OR
  - Implement more stringent approach and hope this is protective of unknown risk (until we can prove one way or the other)
- Complexity and data requirements for RAs are increasing

Example: Use of EL_{10}

- Effect level of 10% supported in draft GD in line with Reg. 283/2013
- Scientifically supported?
  - ~20% effects detectable in B&M studies
  - Ecological relevance: 10% for all endpoints doesn't make sense. What evidence?
  - Behaviour: "*Effects of 10% or greater will be considered relevant, unless extensive literature/data is provided that this is not the case*". How to measure? Onus placed on applicant to prove not ecologically relevant
- Draft argues that ELL_{10} would not significantly change screening/tier 1 RA[3] – so what is the benefit..? Has monitoring demonstrated NOAEL not protective?

[3]Comparison of NOEC values to EC10/EC20 values, including confidence intervals, in aquatic and terrestrial ecotoxicological risk assessment. EFSA Supporting publication. 2015:EN-906

Example: Use of fTWA

- fTWA included in LT assessments to account for degradation of a.s.
- Default TWA = 0.53 (assuming LT exposure = LT effects, 21d averaging period, and DT_{50} 10 days)
- New Draft: need to prove LT effects are not caused by ST exposure (both critical and higher effect endpoints from B&M LT studies)
- Examples given for where not appropriate to use fTWA, some where case-by-case needed, few where fTWA can be considered appropriate
- Could be sig. extra work for applicants, regulators, EFSA… where is evidence previous approach not protective?

Risk assessor's view - conclusions

- Two examples provided where the RA will become more complex
- Not clear if new approaches will provide greater protection (or give the same outcome with greater effort)
- No evidence available as to why current approaches were considered under protective
- Could B&M population monitoring since EFSA (2009) implementation help?

tier3: Practitioner's view on higher tier studies

+ all routes of exposure taken into account

- high variability

Sufficiently worst-case environmental scenario to cover the extremes of possible species exposure and vulnerability

+ real species present in the field

- uncertainty

+ direct measurements under realistic field conditions

+ possibility to reduce uncertainties about a risk

- difficulty to exclude a risk

Request for additional data

- Landscape characteristics provided by habitat mapping
- Recent use of pesticides / agricultural practices not practicable for large-scale studies
- Assessment of food availability – What is worst case?

Further considerations

- Agricultural activities cannot be avoided in large-scale studies and might attract animals
- Full tillage practices may represent worst-case conditions

PT studies

- Choice of focal species
- Duration of a tracking session depending on activity period of species (diurnal/nocturnal)
- Tracking sessions of one individual on non-consecutive days

PD studies

- PD represents the diet selection from a specific area rather than general diet
- Reduce handling stress by observing foraging individuals

Practitioner's view - conclusion

- The new draft B&M guidance strengthens higher tier studies.
- Some additional data requests need further specification.
- Higher tier studies offer most realistic approach to assess risks from PPPs if conducted appropriately.

Thank you for listening!

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