Reflections On Bird And Mammal Risk Assessment: past, present and future

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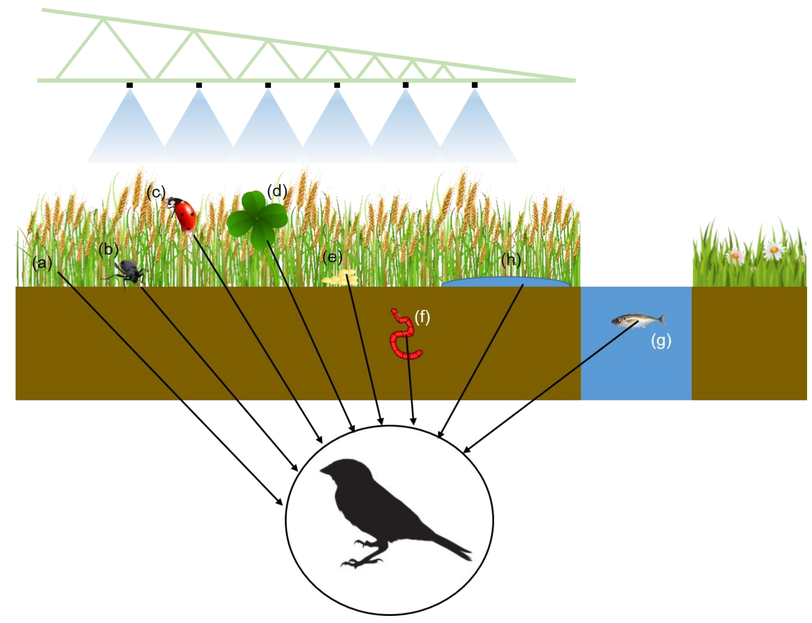
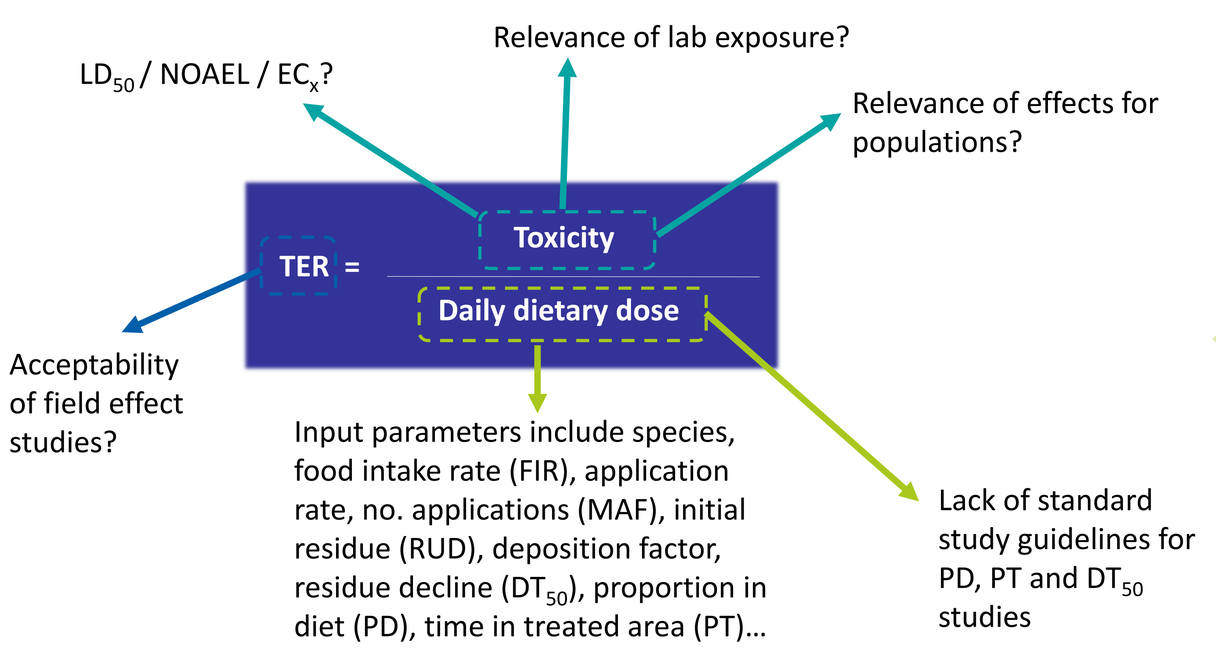
Why assess the risks?
Wild birds and mammals living and feeding in agricultural habitats are potentially exposed to plant protection products (PPPs), used to protect crops from various pests and diseases.

E.g. birds feeding in a treated cereal crop can be exposed by feeding on the crop itself (a), ground-dwelling (b) or foliar-dwelling (c) invertebrates, weeds (d) or weed seeds (e). Birds may also feed on earthworms living in the treated soil (f) or fish living in neighbouring contaminated surface waters (g). Exposure may also occur by drinking from contaminated puddles within the treated crop area (h).

Protection goals (PGs):
- Make mortality or reproductive effects unlikely (surrogate PG)
- Clearly establish no visible mortality and no long-term repercussions for abundance and diversity (Actual PG)





How do we currently assess the risks?
We currently use the scheme produced by EFSA in 2009[1].

A tiered approach is followed, in which toxicity exposure ratios (TERs) are calculated using worst-case (Tier I) or more realistic (higher-tier) parameters. Weight-of-evidence approaches are used in some cases.

TER values calculated using estimates of toxicity and daily dietary dose and then compared to trigger values.

Varying levels of uncertainty in each input parameter, in terms of extrapolation to wild bird and mammal populations.

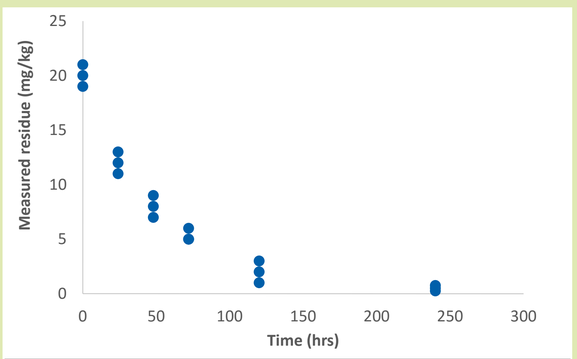
How could the current approach be improved?

Collate database of key focal species and ecological parameters for different crop scenarios across Europe using available industry and generic data and identify knowledge gaps for future research.

Revisit the relevance of the vole scenario, in terms of their occurrence within Europe, their population dynamics and their relationships with crops to help address existing differences in regulatory decisions between Member States.

Develop clear guidance on which PT values to use and when to improve consistency in interpretation of field radiotracking studies between regulators.

Expansion of the RUD database to include residue data collected since the publication of EFSA (2009), improving the robustness of the current database.



Revisit default DT_{50} in food items; available industry data suggest the DT_{50} in plants is often quicker than 10 days and is not significantly affected by rainfall, region or plant type. Also, the development of validated guidelines for conducting studies would improve study quality and thus regulatory acceptability.

Further guidance on deriving bird and mammal reproductive endpoints, in terms of the relevance of different types and levels of effect for assessing the risks to wild populations. Guidance on the use of benchmark dose modelling (BMD) as a refinement option would also be beneficial.

Aim to increase harmonisation between Member States in their evaluation of higher-tier approaches to reach robust and consistent decisions, saving time and money for regulators and industry alike. Clear and effective guidance for specific approaches used within the regulatory zones, driven by differences in climatic and cropping conditions etc, is also required.

Develop more detailed guidance to aid the use and interpretation of modelling approaches (e.g. population models, individual based models) to contextualise risk assessments. Modelling approaches may also assist in extrapolating risk assessments between Member States.

Conclusions

EFSA (2009) was a big step forward from the previous scheme (EC 2002)[2] but there are still significant areas of improvement required for the future.

The ultimate aim for performing a bird and mammal risk assessment is to protect wild populations effectively using ecologically relevant scenarios in risk assessments, finding an appropriate balance between addressing uncertainty and the resulting data burden. It is important to utilise all the available data to update the approaches that we currently have. We should also aim for true harmonisation across the EU Member States in terms of acceptability of refinement options, but acknowledging that the selection of focal species will vary between climatic regions.

In order for a realistic and useable guidance document to be produced in the future, it is therefore vital that there is open and constructive communication between industry, regulatory authorities of Member States and EFSA. Such collaboration would encourage harmonisation between Member States in the interpretation and implementation of the guidance document, thus reducing the workloads for both industry and also regulatory authorities. Furthermore, this would ensure an equal level of protection across the EU.

This poster is based on a draft manuscript to be submitted as a *Focus* article to IEAM.

References:[1]EFSA (2009) Guidance document on risk assessment for birds and mammals on request from EFSA. EFSA Journal, 7, 1438 [139 pp.];
EC (2002) Guidance document on risk assessment for birds and mammals under Council Directive 91/414/EEC. SANCO/4145/2000 – final 25 September 2002, pp 74.