Letter to the Editor

Response to David R. Crocker and Steven D. Langton "When Is It Legitimate to Downplay Individual Differences?"

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Authors' Response:

In their letter, Crocker and Langton (2019) critically discuss the approach of 21-d Monte Carlo PT (portion of diet from a pesticide-treated area) simulations proposed in Ludwigs et al. (2017). The aim of this method is to assess realistic 21-d PT values by including daily variability in habitat use for individual animals. Crocker and Langton (2019) believe that the method described by Ludwigs et al. (2017) is 1) unsuited to most radiotracking datasets; 2) statistically not valid; and 3) could lead to misleading and unprotective risk assessment. In our letter, we want to respond to the comments and concern raised by Crocker and Langton (2019). We still believe that use of the 90th percentile value for many PT datasets, irrespective of data quantity and quality, does not provide a good representation of exposure over the regulatory default time window of 21 d. Therefore, intra-individual variability of daily PT values, if available, should be taken into account. Our 2017 publication used one dataset as an example of how this could potentially be achieved. Of course, some datasets might be unsuitable for such an approach, and depending on the available data and potentially new data, the statistical approach and pooling of data might need to be adapted as well. However, if these points are addressed appropriately in the future, the method would in our opinion not lead to misleading and unprotective risk assessments. A follow-up publication using different datasets for other species is in preparation, to further demonstrate the benefits and constraints of our proposal.

Unsuitability of datasets

It is true that our proposed method may not be suitable for all radiotracking datasets, and we have already highlighted that issue in our 2017 study, for example, we included a suggestion to increasingly include repeated tracking in future studies. Regarding the number of individuals and repeated tracking, our 2017 case study with woodpigeons in farmland is probably one of the largest datasets available, and that is why we selected it to demonstrate our general thinking. Our follow-up publication will investigate the suitability of other, less comprehensive datasets, and how species (and their ecology) and season can be considered. The results of the 2 publications could potentially be used to give guidance as to how data should be analyzed and how new data should be collected (e.g., number of individuals tracked, number of tracking sessions/individual). Based on the results of our 2 publications, it is quite possible that we can also conclude that for some datasets, a Monte Carlo simulation approach is currently not feasible and more data need to be collected. Nevertheless, this does not jeopardize the overall concept that intra-individual variability in daily habitat use should be taken into account in estimating long-term PT values, which can be used for higher tier risk assessment according to the guideline of the European Food Safety Authority (2009).

Statistically not valid

Our target was to approach a long-term pesticide-treated food value corresponding to the relevant 21-d exposure period used as the default under the EFSA guideline (European Food Safety Authority 2009). Clearly, the best dataset for such a purpose would consist of a large enough sample size of radiotagged animals (usually ~20 is considered sufficient) that are each tracked over 21 d. Since this is practically impossible for logistical and cost reasons, our idea is to expand the available radiotracking data with Monte Carlo simulations. It is unclear why Crocker and Langton (2019) call that incorrect because they also use these methods in their letter. The specifics of the approach to check, and account for, inter-/intra-individual variability and finally pooling data are, however, arguable and probably need to be re-evaluated case by case. For instance, Crocker and Langton (2019) advocate averaging the repeated session PT value for each individual and calculating the 90th percentile over these averages. However, using this dataset, some individuals would then be represented by 3 repeated tracking sessions and others by 6 repeated tracking sessions, which could lead to "bias toward" individuals that are tracked more often, but as shown by our proposals it is an example of how to consider variability. With their parametric bootstrap approach, Crocker and Langton (2019) seem to only

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inflate the sample size, which would basically lead to the same result as when calculating the 90th percentile of the empirical data. Our proposed method aims to find a balance for including intra- and inter-individual variability by expanding and evaluating a good but still imperfect dataset, rather than ignoring variability as the title of the Crocker and Langton letter seems to imply. In our opinion, one must always take into account the quality and distribution of data together with ecological knowledge, when judging options for pooling or using PT datasets to obtain a final PT value according to EFSA (2009) for the risk assessment use. If and how data are pooled are points of discussion.

Potential for misleading and unprotective risk assessment

The EFSA guideline (European Food Safety Authority 2009, Appendix A) outlines more than 500 different species/crop scenarios for assessment depending on the timing of the pesticide application. Therefore, neither our study (2017) nor the letter of Crocker and Langton (2019) is dealing with "avian risk assessment" in general. Thus, the overall statement by Crocker and Langton (2019) that "pooling data between individuals will lead to less protective (avian) risk assessments" falls short and trivializes the issue to a black and white position. We agree fully with Crocker and Langton (2019) that a critical look at the data is necessary to avoid the possibility that the PT values used will lead to unprotective risk assessments. The key question is whether a refined risk assessment is more realistic, but will still provide an appropriate level of protection. The protection goal in the EFSA guideline (European Food Safety Authority 2009) for long-term risk assessment on birds is the population level rather than the individual bird. Thus, the focus is not on the individual worst-case bird, as apparently advocated by Crocker and Langton (2019). Furthermore, the current manner of using radiotracking data from field studies for regulatory decision-making in the European Union limits the acceptable data to the so-called consumers, that is, those birds that were actually using the target crop during their tracking session. This approach already includes an additional layer of "protectiveness." because birds that did not choose to forage at all in the target crop are simply disregarded in the estimation of the species long-term exposure assessment. Therefore, we feel that our approach of considering both the intra- and inter-individual variability indicates the appropriate direction for how an assessment could be performed at the local population level, with the specific assessment depending on both the biology of the target species and the composition of the corresponding radiotracking dataset at hand.

As already mentioned, we are working on a follow-up publication with the aim of illustrating this issue for other species and for different radiotracking datasets.

REFERENCES

Crocker DR, Langton SD. 2019. Letter to the Editor: When is it legitimate to downplay individual differences? *Environ Toxicol Chem* 38:1601–1603. (this issue). DOI: 10.1002/etc.4456.

European Food Safety Authority. 2009. Guidance of EFSA—Risk assessment for birds and mammals. *EFSA J* 7:1438. Parma, Italy. [cited 2019 June 20]. Available from: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1438.pdf

Ludwigs J-D, Ebeling M, Fredricks TB, Murfitt RC, Kragten S. 2017. Appropriate exposure estimates for wildlife risk assessments of crop protection products based on continuous radio telemetry: A case study with woodpigeons. *Environ Toxicol Chem* 36:1270–1277.

