*Environmental Toxicology and Chemistry*—Volume 41, Number 10—pp. 2595–2602, 2022
Received: 11 March 2022 | Revised: 26 April 2022 | Accepted: 17 July 2022


Hazard/Risk Assessment

# Predicted Dermal and Dietary Exposure of Bats to Pesticides

Amy C. Brooks,[a,*] Joachim H. Nopper,[b] Alex Blakey,[c] Markus Ebeling,[d] Manousos Foudoulakis,[e] and Arnd Weyers[d]

[a]Cambridge Environmental Assessments, Cambridge, United Kingdom
[b]BASF, Limburgerhof, Germany
[c]Syngenta, Jealott's Hill International Research Centre, Bracknell, United Kingdom
[d]Bayer AG, Crop Science Division, Monheim, Germany
[e]Corteva Agriscience, Halandri, Greece

Abstract: Wild birds and mammals that feed in agricultural habitats are potentially exposed to pesticides through various routes. The European Food Safety Authority (EFSA) recently published a statement which concluded that the current EFSA risk assessment scheme for birds and mammals does not adequately cover bats (Chiroptera). In the present study, we take a more detailed look at the EFSA statement and assumptions made regarding direct (dermal) and indirect (dietary) exposure of bats to pesticides in terms of their realism and the potential implications for risk assessment outcomes. Regarding dietary exposure, errors in the residue per unit dose (RUD) values for flying insects (bat food), proposed in the EFSA bat statement, were identified and corrected. Lower RUD values based on a much broader data base are proposed. Using these more realistic RUD values, together with current assumptions regarding toxicity and exposure, the acute and long-term risk to bats appears to be within the range of those calculated for birds and ground-dwelling mammals under the current risk assessment scheme. Depending on the assumptions made, some uncertainties may remain and should be investigated further. According to the EFSA bat statement, dermal exposure of bats is the most significant route of exposure, resulting in the highest predicted daily doses. We demonstrated that the dermal exposure models in the EFSA bat statement predict much higher residues for bats than those measured for other flying organisms that have larger surface area to volume ratios, and thus would be expected to have the reverse relationship. We also illustrated that the amounts of spray liquid required to achieve the predicted dermal exposures of bats are implausibly high, with bats carrying an amount of spray liquid that exceeds their body weight many fold. It is recommended that a bat risk assessment framework should be based on realistic, sound science, allowing resources to be focused on those scenarios that are not already covered by the existing bird and mammal framework. Therefore, a quantitative risk assessment scheme should not be implemented until the many scientific uncertainties within the EFSA bat statement are addressed. *Environ Toxicol Chem* 2022;41:2595–2602. © 2022 Cambridge Environmental Assessments. *Environmental Toxicology and Chemistry* published by Wiley Periodicals LLC on behalf of SETAC.

Keywords: Bats; Chiroptera; Plant protection products/pesticides; Risk assessment; Exposure; Oral; Dermal

## INTRODUCTION

Wild birds and mammals that feed in agricultural habitats are potentially exposed to pesticides through various routes (Brooks et al., 2017). The risks to wildlife from exposure to pesticides are assessed in the European Union (EU) under the current regulation (Regulation, 1107/2009; European Commission, 2009) for the active substances and formulated plant protection products (PPPs). The current guidance for assessing the risks to birds and mammals from potential exposure to pesticides in the EU was published by the European Food Safety Authority (EFSA) in 2009 (EFSA, 2009) and is currently under review (EFSA, 2021).

Until recently, it has been implicitly assumed that the EFSA (2009) risk assessment scheme for birds and mammals also covered the potential risks to flying mammals, bats (Chiroptera). However, some publications (e.g., Stahlschmidt & Brühl, 2012) raised concerns regarding the protectiveness of the current guidance for bats. Given the ecology and characteristics of bats and their economic value (e.g., Boyles et al., 2011), and the protected status of all 53 European bat species, a review of the protectiveness was considered "vital" by the Panel on Plant Protection Products and their Residues (PPR)


* Address correspondence to amy.brooks@cea-res.co.uk
Published online 22 July 2022 in Wiley Online Library (wileyonlinelibrary.com).
DOI: 10.1002/etc.5438

and, in 2019, they published a scientific statement regarding the coverage of bats by the current risk assessment framework for birds and ground-dwelling mammals (ESFA, 2019a). EFSA (2019a), hereafter referred to as the "EFSA bat statement," concluded that "bats would not be adequately covered by the current risk assessment scheme" and that there is a need to develop a new scheme for bats.

A critical review of the assumptions and evidence-base used in the EFSA bat statement can be found in Brooks et al. (2021). In the present study, we take a more detailed look at the methods proposed in the EFSA bat statement for predicting dietary and dermal exposure of bats, their realism, and the potential implications for risk assessment outcomes.

The main dietary exposure route for bats in the EFSA bat statement is via predation of flying insects that have already been exposed to pesticides. The level of residues within the flying insects is therefore a critical parameter in estimating the dietary exposure of bats. The EFSA bat statement used data from an EFSA supporting publication (Lahr et al., 2018) for this purpose, consisting of regulatory studies submitted to the EFSA by registrants and one literature study. Although 17 measurements of residues in flying insects from nine different studies were included in the Lahr et al. database, only three measurements from studies where light traps were used to capture small flying insects were considered relevant for bats. Studies of fast-acting active substances had been excluded by EFSA and our data set because these may have been biased toward samples with low residues. The three measurements used in the bat statement were all taken from a single study (Stahlschmidt & Brühl, 2012) where an overall worst-case residue unit dose (RUD) of 32.8 mg a.s./kg food/kg a.s./ha was recommended for use in the acute exposure assessment for bats, and a mean RUD of 18.8 mg/kg for long-term exposure assessments. In the present study, we correct errors in the EFSA bat statement regarding the interpretation of these data and use these corrected data, together with additional available residue data, to allow more robust, realistic estimates of flying insect RUDs. We have included additional (malaise and car netting) trapping results, because there are no data to support why only insects caught in light-traps would constitute bat prey and also incorporate non-moth species relevant for bat diets. Also, in the most recent study (Bayer AG, 2021), we included residue data from studies in which both malaise and light traps were used to collect flying insects. We also discuss the implications of these data for the protectiveness of the existing bird and mammal risk assessment framework for bats.

According to the EFSA bat statement, bats may forage in agricultural areas as pesticides are being sprayed onto crops, and thus potentially experience dermal exposure via direct overspray. In the present study, we examine the assumptions made in the EFSA bat statement regarding dermal exposure estimates. We compare predictions from the dermal exposure models in the EFSA bat statement to actual measured residues on other flying organisms to determine how realistic these estimates are. We also estimate the spray liquid loadings that would need to be experienced to achieve the predicted dermal exposures, and how likely these are to be achieved.

# METHODS

## *Residue data for flying insects*

First, we critically evaluated the flying insect residues from Lahr et al. (2018) that were used to calculate RUDs in the EFSA bat statement. The calculation of RUDs was examined to ensure calculations had been performed in line with EFSA guidance correctly, taking into account repeated pesticide applications and ensuring RUDs have been correctly converted to mg/kg per 1 kg a.s./ha applied. Furthermore, concordance with the recent EFSA statement on recurring issues in ecotoxicology (EFSA, 2019b) was checked in terms of using maximum measured residues resulting from the first application event.

Additional data on flying insect residues available from field studies not already included in Lahr et al. (2018) were collated. In total, an additional 41 data points from 11 studies for 11 active substances were available from industry companies, with studies performed in orchards, vineyards, cereals, and oilseed rape crops in the EU. Flying insects were captured using light traps, car netting, or malaise traps. The Bayer AG studies can be requested on the Bayer AG transparency website (https://www.bayer.com/en/agriculture/safety-study-report-request-forms).

Flying insect RUDs were calculated based on the maximum residues resulting from a single application, even if this maximum value was measured after the day of pesticide application. As recommended by EFSA, only studies without fast-acting insecticides were included to prevent bias toward lower residues because only those insects with low residues would be able to reach the sampling device. In three studies (Bayer AG, 2013, 2015, 2021), initial residues included the parent active substance and a major metabolite that was formed very quickly. In these cases, parent and metabolite (expressed as parent equivalents) were added up and treated as if parent residue only.

The corrected data from Lahr et al. (2018) were consolidated with the additional available data on flying insect residues to allow calculation of RUDs based on this larger, more robust dataset. Several studies consisted of more than one trial and analyzed more than one active substance, and for some active substances several studies were available. To assess if the RUD values or variability were affected by active substance properties or study conditions, the data were analyzed per data point (one active substance in one trial), per active substance, and per study.

To determine the protectiveness of the existing bird and mammal risk assessment scheme (EFSA, 2009) for the potential exposure of bats, the same approach as used in Section 3.2.2 of the EFSA bat statement was taken. The shortcut values (SVs; calculated by dividing food intake rate [FIR] by body weight, then multiplying by RUD) for acute and long-term risk to bats were calculated using the FIR/body weight of 0.848 g fresh weight/g body weight/day for *Myotis lucifugus* (as used in the EFSA bat statement) and the new RUD values presented in our study. These were then compared to the Tier I shortcut values in annex I of EFSA (2009) for insectivorous birds, insectivorous mammals, and small herbivorous mammals. These shortcut

 

values were then used in a hypothetical risk assessment for a realistic use on orchards (1 × 100 g a.s./ha, applied at any growth stage), assessed according to EFSA (2009), to assess the protectiveness of the existing bird and mammal scenarios for bats.

### Dermal exposure estimates

The EFSA bat statement proposes that the dermal exposure of bats (*de*) can be predicted by multiplying the volume of air that a bat passes through (*v*) by the proportion of pesticide coming into contact with the surface of the bat (*i*) and by the air concentration (*ac*) per unit body weight (*bw*; Equation 1).

$$de = v \times i \times \frac{ac}{bw} \quad (1)$$

Three models are presented in the EFSA bat statement that could be used to estimate the air concentration component of dermal exposure (*ac*): (1) the even distribution method, (2) the terrestrial investigation model (TIM), and (3) the drift area method. Dermal exposure estimates are presented in Table 7 of the EFSA bat statement for all combinations of bat type (hawker/gleaner), time spent in spray cloud (1 min/2 h), flight speed (fast/slow), and *ac* model (even distribution method/TIM/drift area method), assuming an application rate of 25 g a.s./ha. In the present study, we convert the predicted dermal exposure values to RUDs to allow comparison to measured RUDs for flying insects observed in treated crops. All other things being equal, RUDs for flying insects would be expected to be higher than for bats due to their smaller size and thus higher surface/volume ratio (EFSA, 2019a).

To convert to RUDs, the bat dermal exposure estimates presented in the EFSA bat statement were multiplied by 40, to convert from an application rate of 25 g a.s./ha to 1 kg a.s./ha. For illustrative purposes, dermal exposure estimates for hawker bats using *ac* models that result in the lowest (TIM: 184–44,108 mg/kg body wt) and highest (even distribution method: 1470–352,863 mg/kg body wt) dermal exposure estimates have been considered. The predicted RUDs resulting from dermal exposure of bats were then compared to those calculated for flying insects.

The dermal exposure estimates from the EFSA bat statement were also used to calculate the amount of spray liquid that a bat would encounter to achieve the predicted level of dermal exposure from a 25 g a.s./ha application. For these purposes, a water volume of 200 L/ha was used, which is considered to be a reasonably low water volume for conventional spraying (e.g., Ganzelmeier & Rautmann, 2000). For illustrative purposes, spray liquid volumes were calculated for the TIM *ac* model (the one that gives the lowest residues) for all combinations of bat type, time spent in spray cloud, and flight speed. Spray liquid volumes were also calculated for the overall worst-case dermal exposure estimate (fast flying hawker spending 2 h in spray cloud, calculated using the even distribution method).

## RESULTS

### Residue data for flying insects

On further examination, the maximum RUD of 32.8 mg a.s./kg food/kg a.s./ha recommended in the EFSA bat statement for use in bat exposure assessments has been calculated incorrectly in two ways. First, the normalizing of the measured residues to take into account the application rate (and thus convert to RUDs) has mistakenly been done twice in the EFSA bat statement. The residues reported in Stahlschmidt and Brühl (2012) were already presented as residues per 1 kg active substance/ha applied, and therefore the RUD "correction" presented in Lahr et al. (2018) and used in the EFSA bat statement was not required. Because the application rate used in the Stahlschmidt and Brühl (2012) study was 150 g a.s./ha, this has resulted in the RUDs being incorrectly calculated as 6.67 (i.e., 1/0.150) times higher than they should be. Therefore, the residue values as presented in Stahlschmidt and Brühl (2012) can be used as RUDs.

Second, it is apparent from the supplementary information for Lahr et al. (2018) that the maximum RUD has been derived from residues measured in small moths after the second application in the Stahlschmidt and Brühl (2012) study. However, for all other trials included in the EFSA bat statement analysis, the maximum measured residue resulting from the first application was used.

The correct RUD values to use from Stahlschmidt and Brühl (2012) are summarized in Table 1.

Based on these corrections, the maximum RUD presented in the EFSA bat statement should have been 4.05 rather than 32.8 mg/kg per 1 kg/ha, which would have a significant impact on the exposure estimates for bats feeding on flying insects. This corrected RUD is based on the residues measured from a single study, and therefore its relevance and reliability is uncertain. To this end, additional data available on flying insects have been collated so that RUD values based on a larger dataset can be derived. The available data, including the corrected RUDs from Stahlschmidt and Brühl (2012), are summarized in Table 2.

Using this consolidated RUD dataset, 90th percentile and mean RUD values have been calculated, which could be used in acute and long-term/reproductive risk assessments, respectively, for bats, and indeed for birds and other mammals where relevant.

Some studies have been done with more than one active substance, which raised some questions about how best to handle these data: (1) all data combined as individual data points, with all collected data across substances and studies (with sometimes several trials per study) treated equally; (2) per trial—combined data per study for several active substances (with arithmetic means across several trials in one study); or (3) per substance—data per substance from several studies (combined as arithmetic mean). To allow a comparison, we calculated results for all three approaches.

The calculated 90th percentile and mean RUDs are summarized in Table 3, using either all available data points ($n = 41$), mean values of data per active substance ($n = 11$), or mean values of data per study ($n = 11$).

**TABLE 1:** Corrected EFSA bat statement RUDs (mg a.s./kg food per kg a.s./ha) for flying insects

| Matrix | RUD used in EFSA bat statement (based on Stahlschmidt & Brühl, 2012 as reported in Lahr et al., 2018) | Corrected RUD based on Stahlschmidt and Brühl (2012) | Explanation for correction |
|---|---|---|---|
| Large moths | 8.93 | 2.21 | RUD presented in EFSA bat statement based on maximum residue measured after second application (1.34) instead of first application (2.21), and incorrectly double counted correction from 150 to 1 kg a.s./ha |
| Small moths | 32.8 | 4.05 | RUD presented in EFSA bat statement based on maximum residue measured after second application (4.92) instead of first application (4.05), and incorrectly double counted correction from 150 to 1 kg a.s./ha |
| Small flying insects | 14.7 | 2.90 | RUD presented in EFSA bat statement based on maximum residue measured after second application (2.20) instead of first application (2.90), and incorrectly double counted correction from 150 to 1 kg a.s./ha |

EFSA = European Food Safety Authority; RUD = residue per unit dose.

As can be seen in Table 3, the mean (5.04–5.42 mg/kg) and 90th percentile (9.35–9.54 mg/kg) RUDs are very similar between the three approaches, as are the measures of variability (SD, coefficient of variation [CoV]), regardless of whether data are analyzed per single data point, per active substance or per study. Therefore, there appears to be little influence of substance properties (which would produce higher between-substances variability) or study methodologies (which would produce higher between-study variability) on the resulting RUD values. The slightly lower geomean values across all data points results from the arithmetic mean used to build data points, and not the geomean of geomeans. As such, we would recommend using the simplest approach and largest dataset, that is the geometric mean across all data ($n = 41$). The database can then be easily expanded by simply adding new residue data sets for flying insects as they become available.

Using this corrected and more extensive database of flying insect RUDs results in a significant reduction in the RUDs compared to those in the EFSA bat statement. For acute risk assessments, a 90th percentile RUD of 9.35 mg/kg could be used instead of the maximum RUD of 32.8 mg/kg proposed in the EFSA bat statement, that is 3.5× lower. For long-term/reproductive risk assessments, a geometric mean RUD of 3.72 mg/kg could be used instead of the mean RUD of 18.8 mg/kg proposed in the EFSA bat statement, that is 5× lower. It should be noted that during the preparation of this manuscript, EFSA, (2021) published corrected lower RUD values for flying insects (geomean = 2.6 mg/kg; 90th percentile = 9.7 mg/kg), which are more aligned with the values proposed in the present study than those proposed in the EFSA bat statement.

To determine the protectiveness of the existing bird and mammal dietary risk assessment scheme (EFSA, 2009) for the potential exposure of bats, the shortcut values for acute and long-term exposure of bats have been calculated (approach used in Section 3.2.2 of EFSA, 2019a) using the FIR/body weight of 0.848 g fresh weight/day for *Myotis lucifugus* and the 90th percentile and geometric mean RUD values proposed in our study. This results in $SV_{acute}$ and $SV_{long\text{-}term}$ values of 7.9 and 4.5, respectively. These have then been compared to the Tier I shortcut value values in Annex I of EFSA (2009) for insectivorous birds (various), insectivorous mammals (shrew), and small herbivorous mammals (vole). For all scenarios (45 out of 45), exposure of bats would be covered by the small herbivorous mammal "vole" scenario, with the $SV_{mean}$ and $SV_{acute}$ values for voles all being above those for bats. For most scenarios (35 out of 45), exposure of bats would be covered by the insectivorous bird scenario, with $SV_{mean}$ and $SV_{acute}$ values for insectivorous birds being below those for bats for 10 out of 45 scenarios (relating to uses in cotton, oilseed rape, orchards, ornamentals/nursery, and sugar beet). None of the insectivorous mammal "shrew" scenarios would be protective of bat exposure, with $SV_{mean}$ and $SV_{acute}$ values for shrews being below those for bats for all 39 scenarios.

Although there are scenarios where the predicted exposure of bats (based on current assumptions) is higher compared to birds and ground-dwelling mammals, it is also important to consider the potential risks from that exposure. For example, if we assume a single application of an active substance on orchards at 100 g a.s./ha applied at any growth stage, the potential risks to several scenarios would need to be assessed according to a conservative tier 1 risk assessment as per EFSA (2009), including small insectivorous bird "tit," insectivorous mammal "shrew", and small herbivorous mammal "vole." If we assume that the acute toxicity to birds and mammals is the same, with an arbitrary but realistic median lethal dose of 1000 mg a.s./kg body weight (the value chosen does not change the outcome: any lower or higher assumed value would produce the same relative result), we would calculate toxicity exposure ratios ($TER_{acute}$) of 73–1874, all of which are significantly above the assessment factor of 10, indicating low risks (Table 4). If a $TER_{acute}$ for bats were calculated, using the FIR/body weight from the EFSA bat statement and the corrected 90th percentile RUD for flying insects proposed in our study (9.35 mg/kg), and we assume that the toxicity to bats is the same as to ground-dwelling mammals, we would calculate a $TER_{acute}$ of 1234 (Table 4). The $TER_{acute}$ for bats is significantly above the trigger of 10 and also within the range of those already calculated for birds and ground-dwelling mammals, and thus has no impact on the overall conclusion of low risks from the EFSA (2009) bird and mammal risk assessment.

 

**TABLE 2:** Summary of available flying insect residue data, including the maximum concentration measured ($C_{max}$) and the residue per unit dose (RUD; residue per kg active substance applied)

| Data source | Crop | Method | Application rate (kg/ha) | $C_{max}$ | RUD | Active substance |
|---|---|---|---|---|---|---|
| Stahlschmidt and Brühl (2012) | Orchard | Light trap | 0.150 | NA | 2.21 | Fenoxycarb |
| | | | 0.150 | NA | 4.05 | |
| | | | 0.150 | NA | 2.90 | |
| Syngenta (2005) | Orchard | Light trap | 1.100 | 1.87 | 1.70 | Paraquat |
| Bayer AG (2004) M-121809-01-1 | Orchard | Car netting | 0.385 | 3.598 | 9.35 | Bitertanol |
| Bayer AG (2012a) M-453376-01-1 | Vineyard | Malaise trap | 0.250 | 0.19 | 0.76 | Fluopyram |
| | | | 0.250 | 1.2 | 4.80 | |
| | | | 0.250 | 0.58 | 2.32 | |
| Bayer AG (2012b) M-460299-01-1 | Vineyard | Malaise trap | 0.700 | 3.5 | 5.00 | Propineb |
| Bayer AG (2013) | Cereals | Malaise trap | 0.375 | 0.39 | 1.04 | Spiroxamine |
| | | | 0.375 | 0.383 | 1.02 | |
| | | | 0.375 | 0.862 | 2.30 | |
| M-529934-01-1 | | | 0.200 | 0.11 | 2.25[a] | Prothioconazole |
| | | | 0.200 | 0.098 | 2.10[a] | |
| | | | 0.200 | 0.313 | 4.55[a] | |
| Bayer AG (2015) | OSR | Malaise trap | 0.125 | 0.91 | 7.28 | Fluopyram |
| M-544190-01-1 | | | 0.125 | 0.31 | 3.45[a] | Prothioconazole |
| Bayer AG (2017a)[b] M-588220-01-1 | Vineyard | Malaise trap | 0.111 | 0.85 | 7.66 | Fluopicolide |
| | | | 0.111 | 0.89 | 8.02 | |
| Bayer AG (2017b)[b] M-588227-01-1 | Vineyard | Malaise trap | 1.667 | 26 | 15.6 | Fosetyl-Al |
| | | | 1.667 | 19 | 11.4 | |
| Bayer AG (2017a,b)[b] M-588220-01-1 M-588227-01-1 | Vineyard | Malaise trap | 0.111 | 1.1 | 9.91 | Fluopicolide |
| | | | 1.667 | 11 | 6.60 | Fosetyl-Al |
| Bayer AG (2018a) | Orchard | Malaise trap | 0.1105 | 0.34 | 3.08 | Fluopyram |
| | | | 0.118 | 1.1 | 9.32 | |
| | | | 0.1155 | 1.12 | 9.70 | |
| M-644049-01-1 | | | 0.1105 | 0.28 | 2.53 | Tebuconazole |
| | | | 0.118 | 0.8 | 6.78 | |
| | | | 0.1155 | 0.76 | 6.58 | |
| Bayer AG (2018b) | Orchard | Malaise trap | 0.110 | 0.35 | 3.18 | Fluopyram |
| | | | 0.95 | 0.84 | 8.84 | |
| | | | 0.102 | 0.61 | 5.98 | |
| M-644048-01-1 | | | 0.110 | 0.35 | 3.18 | Tebuconazole |
| | | | 0.95 | 0.76 | 8 | |
| | | | 0.102 | 0.47 | 4.61 | |
| Bayer AG (2021) | Orchard | Light trap | 0.150 | 0.023 | 0.150 | Spirotetramat |
| | | | 0.150 | 0.24 | 1.620 | |
| | | | 0.150 | 0.108 | 0.720 | |
| M-767187-01-1 | | Malaise trap | 0.150 | 0.59 | 3.950 | |
| | | | 0.150 | 0.9 | 6.000 | |
| | | | 0.150 | 0.92 | 6.140 | |

[a]Expressed as sum of parent and main metabolite at first sampling.
[b]This entry is split, because it is one study but in two separate reports for data sharing between companies.

**TABLE 3:** Ninetieth percentile, geometric mean, and mean RUDs, SD, and CoV (%) based on the data in Table 2

| | All data ($n = 41$) | Per a.s. ($n = 11$) | Per study ($n = 11$) |
|---|---|---|---|
| Geomean RUD (mg/kg) | 3.72 | 4.30 | 4.25 |
| Arithmetic mean RUD (mg/kg) | 5.04 | 5.21 | 4.93 |
| 90% percentile RUD (mg/kg) | 9.35 | 9.35 | 9.35 |
| SD | 3.43 | 3.23 | 2.77 |
| CoV (%) | 68.10 | 62.01 | 56.13 |

Cov = coefficient of variation; RUD = residue per unit dose.

A similar conclusion can also be made for the reproductive risks to bats. Using an arbitrary but realistic reproductive toxicity endpoint (no observed adverse effect level) of 10 mg a.s./kg body weight/day for both birds and mammals, the $TER_{repro}$ values for "tit," "shrew," and "vole" would be 10.4, 98.0, and 2.6, respectively, compared to a $TER_{repro}$ for bats of 60 (Table 4). The "tit" and "shrew" scenarios are both above the trigger of 5, indicating low risks, whereas the "vole" scenario would require further assessment, being <5. Therefore, not only is the $TER_{repro}$ for bats significantly above the trigger of 5, it is also within the range of those already calculated for insectivorous birds and mammals, and thus has little impact on the overall conclusion of risks from the EFSA (2009) bird and mammal risk assessment.

**TABLE 4:** Risk assessment calculations for birds and mammals for a hypothetical use on orchards (1 × 100 g a.s./ha, applied all year)

| Growth stage/ timing | Application rate (kg a.s./ha) | Generic focal species[a] | FIR/bw[a] | Diet[a] | RUD[b] | DT50[a] | DDD (mg a.s./kg bw/day)[c] | Toxicity (mg a.s./kg bw/day)[d] | TER[e] | Assessment factor[f] |
|---|---|---|---|---|---|---|---|---|---|---|
| *Acute risk* | | | | | | | | | | |
| Spring, summer | 0.1 | Small insectivorous bird "tit" | 0.86 | 100% foliar insects | 54.1 | 1 | 4.7 | 1000 | 215 | 10 |
| Crop directed, BBCH <10 | 0.1 | Insectivorous mammal "shrew" | 0.55 | 100% ground arthropods | 9.7 | 1 | 0.5 | 1000 | 1874 | |
| Crop directed, BBCH <10 | 0.1 | Small herbivorous mammal "vole" | 1.33 | 100% grass | 102.3 | 1 | 13.6 | 1000 | 73 | |
| Spring—autumn | 0.1 | Hawker bat | 0.848 | 100% flying insects | 9.35 | 1 | 0.8 | 1000 | 1234 | |
| *Reproductive risk* | | | | | | | | | | |
| Spring, summer | 0.1 | Small insectivorous bird "tit" | 0.86 | 100% foliar insects | 21 | 0.53 | 0.96 | 10 | 10.4 | 5 |
| Crop directed, BBCH <10 | 0.1 | Insectivorous mammal "shrew" | 0.55 | 100% ground arthropods | 3.5 | 0.53 | 0.1 | 10 | 98.0 | |
| Crop directed, BBCH <10 | 0.1 | Small herbivorous mammal "vole" | 1.33 | 100% grass | 54.2 | 0.53 | 3.8 | 10 | **2.6** | |
| Spring—autumn | 0.1 | Hawker bat | 0.848 | 100% flying insects | 3.72 | 0.53 | 0.17 | 10 | 60 | |

[a]As defined in Annex I of EFSA (2009), with the exception of "hawker bat," which is taken from EFSA (2019).
[b]As defined in EFSA (2009), with the exception of the RUD values for bats, which are from the extended residue database presented in our study (Table 2).
[c]DDD calculated according to EFSA (2009), that is application rate × FIR/bw × RUD × DT50.
[d]Toxicity endpoints of 1000 and 10 mg/kg bw/day for acute and reproductive risks, respectively, have been chosen arbitrarily.
[e]TER calculated according to EFSA (2009), that is toxicity/DDD. Values in bold are below the relevant assessment factor.
[f]Low risks are concluded for TER values above the relevant assessment factor, as defined in EFSA (2009).
Calculations according to EFSA (2009) for birds and ground-dwelling mammals. Parameters for bats taken from EFSA (2019) and from the extended residue dataset presented in the present study.
bw = body weight; DDD = daily dietary dose; DT50 = half-life, time taken for an amount of compound to be reduced by half through degradation; EFSA = European Food Safety Authority; RUD = residue per unit dose; TER = toxicity exposure ratio.

### *Dermal exposure estimates*

The dermal exposure estimates calculated in the EFSA bat statement for hawker bats using the model with the lowest (TIM) and highest (even distribution method) residue values *ac* model have been converted to RUDs in Table 5.

Based on the calculations in Table 5, the lowest $RUD_{dermal}$ for hawker bats would be 7360 mg/kg and the highest would be 14,114,520 mg/kg (14.1 kg/kg body wt). These exceed the RUD values for flying insects proposed above by orders of magnitude.

The spray liquid volume that would need to be encountered to achieve these predicted dermal exposure residues has been calculated for the same scenarios as presented in Table 5, assuming a hawker bat body weight of 5 g (*Pipistrellus pipistrellus*, based on EFSA bat statement) and a reasonable low spray volume (Table 6). While there are some specific low-volume applications being used by farmers, conventional spray volumes for arable crops are in the range of 200–600 L/ha and typically higher in tall crops such as orchards and vines. For example, United Kingdom Chemicals Regulation Division requires additional information to be supplied for "reduced water volumes" below 200 L/ha on labels (Health and Safety Executive, 2020). Ganzelmeier and Rautmann (2000) use >300 L/ha for drift trials and the Food and Agriculture Organization of the United Nations (2001) consider 150–300 L/ha as conventional spray volumes. A value of 200 L/ha was therefore selected as a reasonably low spray volume.

The lowest amount of spray liquid required to achieve the predicted dermal exposure residues is 8 g, which is 1.6× higher than the body weight of a small bat such as *P. pipistrellus* (body wt = 5 g). The highest amount of spray liquid required to achieve the predicted dermal exposure residues is 14,112 g (>14 kg).

## DISCUSSION

The residues on food items are a key factor in a dietary isk assessment of birds and mammals. The RUD values proposed in the EFSA bat statement for flying insects (mean = 18.8 mg/kg, 90th percentile = 32.8 mg/kg) contained errors leading to very high RUD conclusions. The corrected values, combined with the additional residue data available for flying insects presented in our study, resulted in much lower RUD values (geometric mean = 3.72, arithmetic mean 5.04 mg/kg, 90th percentile = 9.35 mg/kg), leading to much lower shortcut values and daily dietary dose estimates for bats than predicted in the EFSA bat statement. It should be noted that during the process of compiling the data above, EFSA, (2021) published a draft revision of the updated bird and mammal guidance, which also included a reference to residues in flying insects. Data were based on Lahr et al. (2018), which is a subset of the studies mentioned above. In the draft guidance, revised RUDs for flying insects were proposed which are much more in line with the values shown in our study, namely a geometric mean of 2.6 mg/kg, an arithmetic mean of 4.6 mg/kg, and a 90th percentile of 9.7 mg/kg.

Using our corrected and extended RUD database, and a hypothetical use on orchards, it was illustrated that the acute and reproductive risks to bats can be within the range of those already calculated for birds and ground-dwelling mammals according to the existing EFSA (2009) scheme, and thus for some pesticide uses there would be no impact on the overall risk assessment conclusion.

According to the EFSA bat statement, dermal exposure of bats is the most significant route of exposure, resulting in the highest predicted daily doses. Using comparative evidence, it has been illustrated in our study that some of the assumptions made in the EFSA bat statement regarding dermal exposure appear to be over-conservative. When converted to RUDs, the dermal exposure estimates for bats (7360–14,114,520 mg/kg) far exceed those predicted for flying insects (maximum of 15.6 mg/kg). This is the opposite relationship of what would be expected given the larger surface area to volume ratio of insects compared to bats. Furthermore, even when the best-case dermal exposure

**TABLE 5:** Conversion of dermal exposure estimates for hawker bats (calculated in the EFSA bat statement for the two models with the lowest (TIM) and highest (even distribution method) RUDs

| Time in spray cloud | Flight speed | Dermal exposure (mg/kg body wt) after 0.025 kg a.s./ha application[a] | $RUD_{dermal}$ (mg/kg per 1 kg a.s./ha)[b] |
|---|---|---|---|
| *Using TIM as* ac *model* | | | |
| 1 min | Fast | 311 | 12,440 |
| | Slow | 184 | 7360 |
| 2 h | Fast | 44,108 | 1,764,320 |
| | Slow | 22,054 | 882,160 |
| *Using even distribution method as ac model* | | | |
| 1 min | Fast | 2490 | 99,600 |
| | Slow | 1470 | 58,800 |
| 2 h | Fast | 352,863 | 14,114,520 |
| | Slow | 176,430 | 7,057,200 |

[a]Taken from Table 7 of the EFSA (2019) bat statement.
[b]Calculated by multiplying dermal exposure by 40 (to convert residues per kg bat expected from 0.025 kg a.s./ha to 1 kg a.s./ha).
EFSA = European Food Safety Authority; RUD = residue per unit dose; TIM = terrestrial investigation model.

**TABLE 6:** Calculation of the amount of spray liquid that would need to be encountered to achieve the predicted dermal exposure estimates for a hawker bat

| Time in spray cloud | Flight speed | Dermal exposure (mg/bat) after 0.025 kg a.s./ha application[a] | Amount of spray liquid (g/bat) that would be carried[b] |
|---|---|---|---|
| *Using TIM as* ac *model* | | | |
| 1 min | Fast | 2 | 16 |
| | Slow | 1 | 8 |
| 2 h | Fast | 221 | 1768 |
| | Slow | 110 | 880 |
| *Using even distribution method as* ac *model* | | | |
| 1 min | Fast | 12 | 96 |
| | Slow | 7 | 56 |
| 2 h | Fast | 1764 | 14,112 |
| | Slow | 882 | 7056 |

[a]Converted to mg/bat using dermal residues in Table 5 and a body weight of 5 g (based on EFSA bat statement for *Pipistrellus pipistrellus*).
[b]Calculated by multiplying dermal exposure in mg/bat with a factor of 8000, based on 200 kg (spray liquid)/0.025 kg (application rate as per EFSA calculation). The unit difference of mg/bat (a.s.) versus g/bat (spray liquid).
EFSA = European Food Safety Authority; TIM = terrestrial investigation model.

model is used, a small bat weighing 5 g would need to collect 1.6× its own body weight in spray liquid to achieve the dermal residues predicted in the EFSA bat statement. If the worst-case dermal exposure model is used, more than 14 kg of spray liquid would need to be collected. Both lines of comparative evidence demonstrate that the assumptions of the simple modelling approach presented in the EFSA bat statement are not plausible. More information is required on bat flight pathways and spray patterns to increase the realism of the dermal exposure estimates (see Brooks et al., 2021).

There are still many uncertainties within the EFSA bat statement, and these should be identified and addressed before a quantitative risk assessment scheme is implemented (Brooks et al., 2021). More research is needed to fill the current gaps in knowledge. The aim should be to construct a risk assessment framework based on realistic, sound science, and for scenarios not already adequately covered by the conventional bird and mammal assessment. This would save time and resources not only for notifiers, but also for regulatory authorities.

*Acknowledgment*—The present study was funded by CropLife Europe.

*Author Contributions Statement*—**A. C. Brooks**: Writing—original draft. **J. Nopper**: Conceptualization; Writing—original draft. **A. Weyers**: Conceptualization; Writing—original draft. **A. Blakey**: Conceptualization; Investigation; Writing—review & editing. **M. Ebeling**: Conceptualization; Investigation; Formal analysis; Writing—review & editing. **M. Foudoulakis**: Investigation; Writing—review & editing.

*Data Availability Statement*—Summaries of the Bayer AG studies can be requested via the Bayer AG transparency website on request (https://www.cropscience.bayer.com/transparency-crop-science).

## REFERENCES


Bayer AG. (2004). *Residues in arthropod prey of birds & mammals after three consecutive applications of Baycor SC 500 (active substance bitertanol) in Italian pome fruit orchards* (Study Report No. M-121809-01-1).

Bayer AG. (2012a). *Residue decline of fluopyram on arthropods after spray application in vines in Germany* (Study Report No. M-453376-01-1).

Bayer AG. (2012b). *Residue decline of propineb and PTU on arthropods after spray application in vines in the Czech Republic* (Study Report No. M-460299-01-1).

Bayer AG. (2013). *Residue decline of spiroxamine and prothioconazole on arthropods after spray application on cereal fields in western Germany* (Study Report No. M-529934-01-1).

Bayer AG. (2015). *Residue decline of fluopyram and prothioconazole on arthropods after spray application on oilseed rape fields in Western Germany* (Study Report No. M-544190-01-1).

Bayer AG. (2017a). *Residue decline of fluopicolide (AE C638206) on arthropods after spray application in vines in Germany and Spain* (Study Report No. M-588220-01-1).

Bayer AG. (2017b). *Residue decline of fosetyl-Al (AE F053616) on arthropods after spray application in vines in Germany and Spain* (Study Report No. M-588227-01-1).

Bayer AG. (2018a). *Residue decline of fluopyram and tebuconazole on arthropods after spray applications in pome fruit orchards in Germany* (Study Report No. M-644049-01-1).

Bayer AG. (2018b). *Residue decline of fluopyram and tebuconazole on arthropods after spray applications in pome fruit orchards in Spain*.

Bayer AG. (2021). *Residue decline of spirotetramat on arthropods after spray applications in citrus orchards in Spain* (Study Report No. M-767187-01-1).

Boyles, J. G., Cryan, P. M., McCracken, G. F., & Kunz, T. H. (2011). Economic importance of bats in agriculture. *Science*, *332*, 41–42.

Brooks, A. C., Fryer, M., Lawrence, A., Pascual, J., & Sharp, R. (2017). Reflections on bird and mammal risk assessment for plant protection products in the European Union: Past, present, and future. *Environmental Toxicology and Chemistry*, *36*, 565–575.

Brooks, A., Nopper, J., Weyers, A., Crosland, H., Foudoulakis, M., Haaf, S., Hackett, M., & Lawrence, A. (2021). Assessing the risks to bats from plant protection products: A review of the recent European Food Safety Authority Statement regarding toxicity and exposure routes. *Environmental Toxicology and Chemistry*, *40*, 2978–2989. https://doi.org/10.1002/etc.5209

European Commission. (2009). Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. *Official Journal of European Union*, *L309*, 1–50.

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

European Food Safety Authority. (2019a). Scientific statement on the coverage of bats by the current pesticide risk assessment for birds and mammals. *EFSA Journal*, *17*(5758), 81.

European Food Safety Authority. (2019b). *Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology* (EFSA Supporting Publication 2019:EN-1673). 117pp. https://doi.org/10.2903/sp.efsa.2019.EN-1673

European Food Safety Authority. (2021). *Draft EFSA guidance-document – Risk assessment for birds and mammals – Version of 29.09.2021 for public consultation*. Retrieved October 1, 2021, from: http://lynxee.consulting/en/europe-efsa-public-consultation-on-updated-bird-and-mammals-risk-assessment/

Food and Agriculture Organization of the United Nations. (2001). Guidelines on good practice for ground application of pesticides. Retrieved August 2, 2022, from: https://www.fao.org/3/y2767e/y2767e.pdf

Health and Safety Executive. (2020). The applicant guide: Reduced water volume: Non-dietary human exposure and efficacy/crops safety risk assessments. UK. Retrieved December 18, 2020, from: https://www.hse.gov.uk/pesticides/pesticides-registration/applicant-guide/reduced-water-volume-operat.htm

Ganzelmeier, H., & Rautmann, D. (2000). Drift, drift reducing sprayers and sprayer testing. *Aspects of Applied Biology*, *57*, 1–10.

Lahr, J., Krämer, W., Mazerolles, V. P., Poulsen, V., Jölli, D., Müller, M., McVey, E., Wassenberg, J., Derkx, R., Brouwer, A., Deneer, J., Beltman, W., Lammertsma, D., Jansman, H., & Buij, R. (2018). *Data collection for the estimation of ecological data (specific focal species, time spent in treated areas collecting food, composition of diet), residue level and residue decline on food items to be used in the risk assessment for birds and mammals* (EFSA Supporting Publication 2018:EN-1513). 155pp. https://doi.org/10.2903/sp.efsa

Stahlschmidt, P., & Brühl, C. A. (2012). Bats at risk? Bat activity and insecticide residue analysis of food items in an apple orchard. *Environmental Toxicology and Chemistry*, *31*, 1556–1563.

Syngenta. (2005). A field study to determine residues of a 200 g/L SL formulation (A3879BV) in apple orchard invertebrates as potential food items for birds and small mammals. (Study Report, No. ZA0148, paraquat).


 