UK HSE position paper on the use of Monte-Carlo simulated PT value

1. Background to the parameter 'PT' in pesticide risk assessment and possibilities for its refinement

In the EU risk assessment for birds and mammals is conducted according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA 2009)[1]. This document provides a tiered approach to assessing both, direct acute and reproductive risk to birds and mammals.

Data requirements

The data required for this risk assessment are set out in Commission Regulations (EU) No. 283/2013[2] and 284/2013[3]. Section 8.1.1 of Commission Regulation 283/2013 covers effects on birds and includes an acute oral toxicity study and a reproductive toxicity study on birds. A short term oral study is only required where the mode of action or results from mammalian studies indicate a potential for the dietary LD_{50} measured by the short- term dietary toxicity study to be lower than the LD_{50} based on an acute oral study. Section 8.1.2 covers effects on mammals and includes an acute oral toxicity study and a reproductive toxicity study on mammals.

Risk assessment

The information from the toxicity studies are compared to estimates of exposure and a "toxicity exposure ratio" (TER) is determined. The TER is then compared to trigger values detailed under Section 2.5.2 of the EU Commission regulation regarding uniform principles[4].

The first step in the process is a 'screening step'. It makes use of an 'indicator species' along with worst-case assumptions regarding exposure. The aim of this step is to highlight those substances that do not require further consideration as their associated uses pose a low risk.

If a substance and its associated use do not pass the screening step, then the next step is the first tier risk assessment. This uses more realistic exposure estimates along with a 'generic focal species'. If this step is not successful, i.e. the TER is found to be below the regulatory trigger value, then further refined risk assessment is required. This involves a greater degree of realism and uses more realistic exposure estimates as well as a 'focal species' approach.

The exposure calculation can either include a mixed diet (for example an omnivorous bird or mammal might consumer a mixture of plant leaves, invertebrates and seeds) or a single diet (for example an insectivorous bird or mammal might consume only ground dwelling invertebrates). The equation to calculate the exposure in each case is slightly different because for a mixed diet each component will have different energy content. For simplicity the

[1] Risk Assessment for Birds and Mammals; EFSA Journal 2009; 7(12):1438

[2] COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

[3] COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

[4] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

description of the exposure model below will therefore focus on the single diet situation (i.e. the below-described ‘PD’ parameter is 1 for the food item considered), noting that the same principles apply if a mixed diet is relevant. Further details regarding PD can be found in Section 6.1.6 of EFSA (2009).

The estimated daily exposure or daily dietary dose (DDD), i.e. the uptake of a compound via a single food item is given by the following equation:

$$DDD = \frac{FIR}{bw} * C * PT$$

In which:

DDD = daily dietary dose in mg/kg bw (acute) or mg/kg bw/d (reproductive)
FIR = Food intake rate of indicator species in g fresh weight /d
bw = Body weight in g
C = Concentration of compound in fresh diet in mg/kg diet food item
PT = proportion of an animal’s daily diet obtained in habitat treated with pesticide (number between 0 and 1). The default is 1 (i.e. the bird or mammal obtains all food from within the treated area).

A higher-tier assessment is required when the results of first tier risk assessments breach the relevant trigger values (e.g. TER < 10 for acute risks, 5 for reproductive risks).

The aim of carrying out the above risk assessment is to ensure that the protection goals for birds and mammals are met. For birds and mammals, there are two types of protection goals, i.e.: actual and surrogate protection goals. The actual and surrogate protection goals are defined as follows:

- The actual protection goal is to provide a high certainty that no visible mortality and no long-term repercussions on abundance and diversity will occur.
- The surrogate protection goal is to make any mortality or reproductive effects unlikely.

Further details are provided in Section 3 and associated Appendices of EFSA (2009).

In higher-tier assessments, either protection goal can be used. It may be possible to show by refined assessment that the surrogate protection goal can be satisfied. However, if this is not possible then it would be necessary to address the actual protection goal directly.

EFSA (2009) lists a range of refinement options including refining the ‘proportion of an animal’s daily diet obtained in habitat treated with pesticide’, or PT in the above exposure equation. This is only relevant for long-term/reproductive risk assessment

Refinement of PT

In order to refine PT relevant ‘focal species’ or FS for the risk assessment need to be identified. These are species that actually occur in the crop when the pesticide is being used. The aim of using ‘focal species’ is to add realism to the risk assessment insofar as the assessment is based on real species that forage within the crop. It is essential that the species are shown to actually occur in the crop at a time when the pesticide is being applied. Further, it is essential that the identified focal species are representative of other species from the same feeding guild (i.e. body size and most importantly consumed food types) that may occur in the crop at that time, as highlighted at earlier stages of the risk assessment.

Appendix M of the EFSA guidance document for bird and mammal risk assessment describes the appropriate generation and use of such information.

Once the relevant focal species have been identified additional data can be used to refine PT. As stated above, PT is defined as the **'proportion of an animal's daily diet obtained in habitat treated with pesticide'**, since it is not possible to directly measure the proportion of the diet obtained from within a treated area it is estimated based on radio-tracking data showing where a bird or mammal spends its time foraging, using the assumption that it will also obtain its diet in proportion to where it spends its active time.

Data from radio-tracking studies are used to provide an estimate of the amount of the daily diet that a bird or mammal obtains from the treated area. In obtaining this data it is necessary to distinguish between the time spent in the crop 'actively or potentially foraging' and the time spent in the crop 'inactive or not foraging' for food, as well as whether an individual is located within the crop, or in the surrounding area. Table 1 is based on Appendix P of EFSA (2009) and shows the definitions of the behaviour categories.

Table 1: Definition of behaviour categories (used for calculation of PT)

<u>Potentially foraging</u> All instances when the bird/mammal was foraging for sure, or might have been foraging	Foraging	Bird/mammal is foraging (e.g. fluctuating radio-tracking signal, supported by visual sightings of bird searching for food).
	Active: Unknown	Bird/mammal is active (e.g. fluctuating radio-tracking signal strength) but more definite information cannot be obtained.
<u>Not foraging</u> All instances where bird/mammal was inactive or clearlt engaged in non-foraging activity	Breeding	Bird/mammal is engaged in behaviours that are part of reproduction (e.g. singing of males, sing flight), copulation, mate guarding, territory defence, incubating (if nest site is known) etc., thus foraging can be excluded.
	Active: Other non-foraging	Bird/mammal is carrying out activities other than foraging and reproduction (e.g. seen preening, bathing, drinking, sunbathing).
	Inactive	Bird/mammal classified as inactive (not moving) by radio-tracking signal and/or by visual contact (thus, foraging can be excluded).

In order to obtain the PT via radio-tracking birds or mammals are either caught in the crop of concern or in the vicinity of the crop of concern.

The behaviour of birds is likely to vary over time based on their needs (e.g. nutritional) during different parts of their reproductive cycle; food availability and habitat structure (e.g. amount of cover). Therefore PT will also vary with these factors, so it is important that PT studies are conducted on the relevant crop and growth stage and the correct time of year with a representative surrounding habitat.

The majority of PT studies considered to-date cover the activity period of a single day, occasionally including a few birds tracked for more than one day, i.e. they have been designed to determine "a day in the life" of a particular bird or mammal. Sometimes shorter observation periods (e.g. 2 hour blocks have been used) and these have been gathered over several days to determine a "day in the life" of a bird or mammal. Further information is provided in Appendix P of EFSA (2009).

The guidance document does not specify the percentile of the distribution of PT values that should be used in the risk assessment but points out that if the first-tier PT of 1 was replaced by a median or mean, this would suggest that the risk assessment will only relate to those 50 % individuals that fall under this PT noting that due to influence of other variables it is not possible to directly relate the percentile of PT used to the percentage of the population protected. This, along with other refinements, should be considered at the end of the risk assessment to determine if either the protection goal or surrogate protection goal have been met.

Discussions between Member States (MS) have resulted in the current practice to be the use of the 90th percentile PT value for all focal species. Provided in Appendix 1 is an example of how a dataset is currently considered and used.

Meeting the protection goals

As outlined above and in Appendix C of EFSA (2009), there is a need to assess the level of conservatism in the refined risk assessment and determine whether either the protection goals or surrogate protection goals have been met.

When considering whether the refined risk assessment for the long-term/reproductive risk to birds or mammals has been met it is necessary to consider the relevance of the focal species as well as any data used to refine PT. As indicated above, it is usual to have radio-tracking data in the form of “a day in the life”, i.e. it represents one days foraging behaviour. In principle, in order to meet the protection goal of long-term/reproductive effects being unlikely, it would make sense to use a value for PT that was obtained over the toxicologically relevant time period, i.e. the period of radio-tracking should cover the part of their reproductive cycle that is vulnerable to the pesticide use under consideration). In order to obtain this value using purely experimental methods a sufficient number of birds would need to be tracked through the relevant reproductive period. Then the average PT of each bird could be calculated and then the 90th percentile of all birds could be calculated (noting that the choice of 90th percentile is an arbitrary selection to describe the majority of birds, but is the percentile typically used in environmental risk assessment to reflect a “reasonable worst case” approach).

It is important to note that the relevant time period of the reproductive risk assessment is the whole reproductive period (or the period of a specific part if only one aspect is impacted). The calculation of the concentration on food is by default calculated using a 21-day time weighted average (TWA), but this is an arbitrary time period identified as suitable to obtain an average residue (balancing the over conservative option of using only the maximum residue, with the under conservative option of averaging over too long a period). Therefore the relevant duration of the reproductive assessment will vary between species, the part of the breeding cycle affects and different toxicological effects.

2. A HSE summary of the paper by Ludwigs *et al.* (2017)

A detailed summary of Ludwigs *et al*. (2017) is presented in Appendix 2.

The aim of Ludwigs *et al.* was to investigate whether an existing dataset for the woodpigeon could be used in order to give an estimation of long-term PT behaviour. The dataset was generated by radio-tracking of woodpigeons trapped in an area of arable farmland in North Yorkshire, UK in the autumn of 2003. Included in the landscape of the study, and defined as the crop of interest for the purposes of the paper, was stubble crop fields which the study (as well as other referenced work) stated is a preferred habitat of woodpigeons. The underlying empirical dataset was selected as it:

- was a good sample size of 20 individual birds,
- involved complete tracking over dawn-to-dusk activity periods and
- included the repeated tracking of individuals, over either one or two instances of three consecutive days.

Hence, on the basis of the above, the dataset was potentially sufficient to provide information on the expected variability of an individual pigeon's behaviour over a longer duration of time. The paper discussed that the current approaches to PT refinement in bird and mammal risk assessments are mainly influenced by the higher end individuals' behaviour on a single day of observation and so insufficient consideration is given to the variability/change over time of such individuals, which might be more in keeping with lower percentile individuals' foraging behaviour.

The paper used a Monte Carlo simulation to derive average long-term (defined in the paper as 21 days) PT values for a hypothetical modelled population constructed using the available data on woodpigeons. In doing so the authors first used a goodness-of-fit test to define which empirical data could be combined and which should be utilised separately in any simulation. Once this was established a total of 1000 hypothetical 'Monte Carlo individual' woodpigeons were modelled – that is had a daily PT predicted for 21 consecutive days – and then a 21-day mean PT calculated for each modelled individual. This modelled population was then plotted as a distribution of mean PT values before calculating a 90th percentile PT for the theoretical population (0.53). This value was compared to a 90th percentile PT value derived using the empirical dataset and calculated by the paper authors to be 0.89, noting that this differs slightly from the HSE worked example given in appendix A.

3. HSE discussion of the 21-d PT concept and Ludwigs *et al*. (2017) example

While it is the concept and approach of using a 21-day PT value that is key, rather than the specifics of this example using wood pigeon data (for example the final PT value of 0.53), the interpretation of the dataset in Ludwigs *et al*. (2017) does provide a useful illustration of some of the issues requiring consideration with such an approach. These issues can be broadly grouped into toxicological, ecological and statistical categories.

<u>Toxicological</u>

- While it is appreciated that 21 days is the default length for calculating time-weighted exposure at screening step/first tier in the EFSA guidance on bird and mammal risk assessment (EFSA, 2009), 21 days is an arbitrary figure and it would be preferable in a higher tier assessment to consider the key toxicological effects for the specific active substance and the exposure period responsible for such effects when selecting an appropriate averaging period for the PT value (though potential changes in surrounding habitats should also be considered, as discussed above). It should be noted that long-term effects can occur as a result of short-term exposure.

<u>Ecological</u>

- PT datasets are specific to the particular species, crop, crop growth stage, surrounding environment and time of year studied. Therefore while a study design and calculation method used for determining a representative PT value may be suitable for one situation, it may not be appropriate for another situation with a different species, crop etc. For example, differences in variability may mean a different number of individuals/sessions need to be tracked or a distribution may or may not fit the underlying data.

- Radio-tracking studies are performed in dynamic environments. In Ludwigs *et al*. (2017) there was a 5-6 week gap between the first and last tracking sessions for some birds. It would have been useful to consider whether there were any changes in the surrounding habitats over this time period that may impact the PT values obtained.
- It is shown in Ludwigs *et al.* (2017) that the 21-day TWA 90th percentile PT value determined using the Monte Carlo method (0.53) is lower than the 90th percentile PT derived using observed 1-day PT values (0.89) or the 90th percentile using all the PT data as described in Appendix 1 (0.678). However, it has not been demonstrated that the 0.53 value represents the more appropriate PT estimate for the population.

Statistical

- Typically empirical PT datasets are relatively small in terms of the number of individuals tracked (usually around 10-20 individuals) and the number of sessions available for each individual (usually one session per individual). This can make understanding and characterising variability and uncertainty in such datasets difficult. The number of data points needed to robustly characterise intra-individual and inter-individual variability is likely to vary between species, crops etc.
- In the example in Ludwigs *et al*. (2017) radio-tracking data has been pooled between individuals and sessions in order to calculate an appropriate PT estimate. It has been assessed whether this approach is justified for individual birds by comparing the variability in PT for an individual to the inter-individual variability in PT. However, this comparison was only carried out for the 6 birds with 6 monitoring sessions and not for the 14 birds with only 3 tracking sessions (see Appendix 2 for details). For the 14 birds with 3 tracking sessions it has been assumed that PT data for these individuals can be pooled without clear justification. This highlights the general issue of how many individuals/tracking sessions are needed to allow for a robust comparison of intra-individual and inter-individual variability.
- Intra-individual and inter-individual variability in PT have been found to be comparable for 4/6 birds where this comparison has taken place (i.e. 67%). This means that the PT data for these individuals can be used in the common pool. However, by assuming that the data for the 14 birds with only 3 tracking sessions can also be included in the common pool, it results in 90% of individuals in the simulated population having PT values taken from the common pool.
- In the wood pigeon example the comparison of intra-individual variability and inter-individual variability uses PT data from session 1 to characterise inter-individual variability but does not consider the available data from sessions 2 and 3. An analysis that uses all the data from all three sessions may provide a more objective assessment of the intra- and inter-variability compared to the apparently arbitrary selection of one session.
- How to utilise PT data when there are different numbers of tracking sessions for different individuals spread unevenly over a number of weeks requires careful consideration. In this dataset, there were fourteen birds that were tracked for 3 sessions and 6 birds were tracked for 6 sessions in Ludwigs *et al*. (2017). The nature

of sampling times and the unbalanced structure of the data suggests a mixed effects modelling approach might be appropriate for assessing the whole dataset. The presence of repeated measures will also require this. There also needs to be careful consideration of fact the PT values are proportions (logistic regression, zero/one inflated beta distribution[5], or a compositional analysis[6] of the underlying 24 hour time-use composition data may be appropriate options).

- Given intra-individual and inter-individual variability in PT and given the size of typical empirical datasets, there will be uncertainty associated with any PT estimate. In the woodpigeon example a single overall PT value was proposed with no confidence intervals. It would have been helpful to include a consideration of uncertainty and robustness in the final outputs – this represents an unutilised benefit of the probabilistic approach adopted.

HSE conclusions/recommendations

The concept of generating a 21-day (or other specific averaging duration) PT value appears a reasonable approach for characterising long-term bird and mammal behaviour. However how to use PT data from multiple individuals and/or tracking sessions in pesticide risk assessment is not well-understood and therefore there are a number of factors that mean case-by-case consideration of how to derive an appropriate PT value will be required and the strength of the underlying dataset will be critical. Therefore the Ludwigs *et al*. (2017) paper represents an important development in the use of radio telemetry data but does not detail a universal method that can be applied to any PT dataset (noting this was not the authors' intention).

When conducting a new radio-tracking study with the purpose of establishing a time-weighted PT value for use in risk assessment, it is recommended to carefully consider the following key points.

1. Study design, e.g. how many tracked individuals and tracking sessions per individual are needed given how the data are to be analysed, what is the nature of surrounding environments and how do these change during the study, what duration and temporal spacing of tracking sessions is appropriate.
2. How to utilise the data produced to calculate an appropriate PT value, e.g. how to make best use of all the data generated, how to compare intra-individual and inter-individual variability, whether a mixed effects model is appropriate, how to characterise uncertainty.
3. How to justify the appropriateness of the method used to analyse the dataset, e.g. in the Ludwigs *et al.* (2017) paper it has not been shown that the method used to characterise PT from the radio-tracking data is more appropriate than another method.

Careful consideration of these same issues is also just as important when using existing radio-tracking studies to determine a time-weighted PT value and further analysis of such data sets will therefore be required for this purpose.

[5] Fang Liu & Evercita C Eugenio, A review and comparison of Bayesian and likelihood-based inferences in beta regression and zero-or-one-inflated beta regression, Statistical Methods in Medical Research 27 (4) 1024-1044, 2018, doi: 10.1177/0962280216650699

[6] Louise Foley, Dorothea Dumuid, Andrew J. Atkin, Timothy Olds, and David Ogilvie, Patterns of health behaviour associated with active travel: a compositional data analysis, International Journal of Behavioural Nutrition and Physical Activty 15:26, 2018, doi: 10.1186/s12966-018-0662-8

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September 2018

Appendix 1

<u>Worked Example of how radio tracking data are interpreted and used in a risk assessment</u>

Presented below is an example of how a dataset is currently considered and used. Table 2 shows the radio tracking results from day 1 from Ludwigs *et al.* (2017). Day one has been selected to illustrate how data on PT are currently considered.

Table 2: Full-day empirical PT values obtained for the habitat stubble field from 20 individual woodpigeons radio-tracked continuously for 1 daylight period in autumn in the United Kingdom (Ludwigs *et al.*, 2017)

	PT value, for stubble field of tracking session number (full-day radio tracking)					
Woodpigeon individual	1	2	3	4	5	6
1	0.546	0.355	1			
2	0.054	0.465	0.110	0.211	0	0
3	0.335	0.603	0.254	0	0	0
4	0.486	0.626	0.217			
5	0	0	0.119	0	0	0
6	0.374	0.052	0.584	0.719	0.158	0.541
7	0.175	0.263	0.479			
8	1	0.526	0.967	0.444	0.429	0.435
9	0.933	0.459	0.113			
10	0.478	0.114	0.140			
11	0.497	0.794	0.530			
12	0.513	1	0.708			
13	0.118	0.314	0.233			
14	0.452	0	0.102			
15	0.447	1	0.923	0.438	0.542	0.487
16	0.140	0	0			
17	0.150	0	0.171			
18	0.399	0.691	0.924			
19	0.778	0.878	0.572			
20	0.366	0	0.069			

<u>Situation 1 20 birds tracked for 1 session only</u>

Step 1:

Check the data set to determine whether

a) The species tracked is the focal species being considered
b) The crop is relevant for the GAP
c) The time of year is relevant for the GAP
d) The landscape is typical of the areas the pesticide will be used in
e) Sufficient numbers of birds have been tracked (target is 20 birds or more)

Step 2:

Check that all birds are consumers i.e. they have a PT of >0. In this case, for tracking session 1 bird number 5 was not a consumer, so if data were only available for this tracking session then this bird would be excluded.

Step 3:

Calculate the 90th percentile of the consumers tracked. This is shown in table 3.

Table 3: 90th percentile of consumers from session 1

Bird number	PT	Comment
1	0.546	
2	0.054	
3	0.335	
4	0.486	
5	0	Bird removed as not a consumer
6	0.374	
7	0.175	
8	1	
9	0.933	
10	0.478	
11	0.497	
12	0.513	
13	0.118	
14	0.452	
15	0.447	
16	0.14	
17	0.15	
18	0.399	
19	0.778	
20	0.366	
90th percentile	0.809	

In this case the PT values used for the risk assessment would be **0.809**.

<u>Situation 2: 20 birds tracked for more than 1 session in some cases</u>

Step 1 and **Step 2** are as above.

Step 3:

If a few of the birds were tracked over more than one day (timing of both tracking sessions still within the relevant time period) then the average value of PT for the tracking sessions can be taken for those birds tracked more than once and this mean value used as the "per bird" PT. For example, if birds 3, 10, 12 and 16 were also tracked at session 2 (and none of the others were) their PT values would be:

Bird 3 = average (0.335 and 0.603) = 0.469
Bird 10 = average (0.478 and 0.114) = 0.296

Bird 12 = average (0.513 and 1) = 0.757
Bird 16 = average (0.14 and 0) = 0.07

Bird 16 did not use the crop during the second tracking session, but since it did use the crop in one of the tracking sessions it is considered to be a consumer.

These values would be used in place of the single tracking session results for the relevant birds and the 90th percentile calculated as above.

Situation 3: 20 birds tracked for 3 or 5 sessions

This example will use the whole data set from Ludwigs *et al.* (2017) and treat it according to the principles established above i.e. determine an average PT for each bird and then calculate the overall 90th percentile PT.

Step 1

As above, although with such a large number of tracking sessions it is particularly important to check that the time period when the tracking took place is relevant for the use being considered. For this tracking data set the telemetry was conducted from 18th September to 12th November and for illustrative purposes it is assumed that this time period is relevant.

Step 2

Although there are some birds that were not consumers at certain tracking sessions all birds have a PT of above 0 on at least one tracking sessions. This is a wide interval, but since in this example we do not have a specific situation under consideration it is assumed that the whole period is relevant. If this is not the case then consideration about removing some tracking sessions is required.

Step 3

Calculate the average PT for each bird and then calculate the overall 90th percentile of these average PTs. This is shown in table 4.

Table 4: Average "per bird" PT and overall 90th percentile using the full data set Ludwigs *et al.* (2017)

Bird number	PT value, for stubble field of tracking session number (full-day radio tracking)						Average PT
	1	2	3	4	5	6	
1	0.546	0.355	1				0.634
2	0.054	0.465	0.11	0.211	0	0	0.14
3	0.335	0.603	0.254	0	0	0	0.199
4	0.486	0.626	0.217				0.443
5	0	0	0.119	0	0	0	0.020
6	0.374	0.052	0.584	0.719	0.158	0.541	0.405
7	0.175	0.263	0.479				0.306
8	1	0.526	0.967	0.444	0.429	0.435	0.6335
9	0.933	0.459	0.113				0.502
10	0.478	0.114	0.14				0.244

Bird number	PT value, for stubble field of tracking session number (full-day radio tracking)						Average PT
	1	2	3	4	5	6	
11	0.497	0.794	0.53				0.607
12	0.513	1	0.708				0.740
13	0.118	0.314	0.233				0.222
14	0.452	0	0.102				0.185
15	0.447	1	0.923	0.438	0.542	0.487	0.640
16	0.14	0	0				0.047
17	0.15	0	0.171				0.107
18	0.399	0.691	0.924				0.671
19	0.778	0.878	0.572				0.743
20	0.366	0	0.069				0.145
90th percentile							0.678

Use in the risk assessment

The impact PT can have on a risk assessment is illustrated using several examples below. The following PT values will be demonstrated:

- Tier 1: PT = 1
- Conventional (data from 1 session) 90th percentile: PT = 0.809
- Conventional (all data included) 90th percentile per bird: PT = 0.678
- Mean PT (all data): PT = 0.378
- Ludwigs *et al.* (2017) proposal: PT = 0.53

This example risk assessment is based on:

- A pesticide used on stubble between September and November (to match the PT data available)
- Woodpigeon (490 g) identified as the relevant focal species
- A diet consisting of 100% weed seeds (arbitrary, but suitable for an illustrative assessment). (resulting FIR/bw of 0.060)
- A mean Residue per Unit Dose (RUD) for seeds of 40.2 from Appendix F (EFSA 2009)
- A single application at 2 kg a.s./ha
- A reproductive toxicity endpoint of 8 mg a.s./kg bw/d

FIR/bw	Application rate (kg/ha)	RUD	ftwa	PT	DDD (mg/kg bw/d)	Toxicity (mg/kg bw/d)	TER	Trigger
0.06	2	40.2	0.53	1	2.56	8	**3.13**	5
				0.809	2.07	8	**3.87**	
				0.678	1.73	8	**4.62**	
				0.378	0.97	8	8.28	
				0.53	1.36	8	5.90	

Figures in **bold** are below the trigger value

In this example the three higher PT values gave TERs below the trigger value (acceptable risk not demonstrated) and the two higher values gave TERs above the trigger (acceptable risk). Whilst this is not a real example the outcome is typical of what you see when PT is varied.

The selection of PT value in a risk assessment can have a very major impact on the result, so it is important to ensure that the most appropriate value is selected.

Appendix 2

A detailed summary of the paper 'APPROPRIATE EXPOSURE ESTIMATES FOR WILDLIFE RISK ASSESSMENTS OF CROP PROTECTION PRODUCTS BASED ON CONTINUOUS RADIO TELEMETRY: A CASE STUDY WITH WOODPIGEONS'; Ludwigs, J-D, Ebeling M, Fredricks TB, Murfitt RC and Kragten S /; Environmental Toxicology and Chemistry, Vol. 36, No. 5, pp. 1270–1277, 2017.

As described in the above background section, typically a worst-case or 90th percentile PT value from the obtained field data is applied in EU regulatory risk assessment, depending on the number of individuals observed, and variability of their foraging behaviour (PT). The below described paper by Ludwigs *et al*. however, proposes a new way to make use of such data for refining the PT parameter for risk assessment.

The empirical dataset used in the paper was foraging behaviour data on woodpigeons trapped and tagged in an agricultural environment within the UK in the autumn of 2003.

Twenty individuals were initially trapped and fitted with radio transmitters before being released. Each individual was then tracked for three consecutive dawn-to-dusk periods, with each tracking period recording the location, duration and (where possible) behaviour of an individual pigeon in stubble fields. Subsequent to this initial tracking activity, six of the radio-tagged individuals (selection criteria unknown) were tracked for a second period of three consecutive days. Overall 78 individual days of information were collected, spanning approximately 8-weeks duration. From this collected dataset on wood pigeons a PT value was first calculated per observed day, PT being the proportion of 'total active time' that the individual spent in the field under consideration (crop stubble) on that day.

Table 1 summarises the per-day PT value of each individual woodpigeon (the complete dataset is presented in Appendix 3). Of note, individuals numbered 2, 3, 5, 6, 8 and 15 were those tracked for a total of 6 daylight periods. Furthermore the dataset (n= 78) included a whole range of PT from zero (no active time spent in stubble crop) to 1.0 (all active time spent in stubble crop). A total of 15 zero PT days were reported, as well as 4 occasions of 100% active time in the crop of interest (i.e. PT = 1).

Table 1: Full-day empirical PT values obtained for the habitat stubble field from 20 individual woodpigeons radio tracked continuously for 1 daylight period in autumn in the United Kingdom[a]

	PT value, for stubble field of tracking session number (full-day radiotracking)					
Woodpigeon individual	1	2	3	4	5	6
1	0.546	0.355	1.000			
2	0.054	0.465	0.110	0.211	0.000	0.000
3	0.335	0.603	0.254	0.000	0.000	0.000
4	0.486	0.626	0.217			
5	0.000	0.000	0.119	0.000	0.000	0.000
6	0.374	0.052	0.584	0.719	0.158	0.541
7	0.175	0.263	0.479			
8	1.000	0.526	0.967	0.444	0.429	0.435
9	0.933	0.459	0.113			
10	0.478	0.114	0.140			
11	0.497	0.794	0.530			
12	0.513	1.000	0.708			
13	0.118	0.314	0.233			
14	0.452	0.000	0.102			
15	0.447	1.000	0.923	0.438	0.542	0.487
16	0.140	0.000	0.000			
17	0.150	0.000	0.171			
18	0.399	0.691	0.924			
19	0.778	0.878	0.572			
20	0.366	0.000	0.069			

[a]Where PT = 1.0 means all active/foraging time spent in stubble and 0 = no active/foraging time spent in stubble.
PT = portion of diet obtained from a treated area.

The narrative of the paper next proposes that "more population-relevant" data might be generated by use of a limited size empirical dataset (as collected from tracking of 20 woodpigeons in this case) to produce a Monte Carlo simulation of a much larger population than that observed. The basic theory of a Monte Carlo simulation is to demonstrate the probability of a particular distribution fitting a much smaller dataset appearing if extrapolated out to a much larger sample size. In extrapolating out the limited empirical dataset the variability of the original data utilised is still reflected. In this instance a Monte Carlo simulation was run on 1000 'Monte Carlo individuals' – that is 1000 hypothetical individuals, for which a mean PT was constructed from 21 randomly selected empirical PT results from the underlying woodpigeon tracking study. Some steps were taken by the authors to check and justify this use of the empirical data to provide a much larger (albeit hypothetical) population:

To allow the use of single empirical PT values to be used as representative of one day of behaviour for a simulated 'Monte Carlo individual' it would first need to be ensured that the variability of PT by a single individual across time were comparable to that between individuals in a comparable situation (i.e. time and environment at observation). To assess this point the distributions of both intra- and inter-individual PT values were tested with the Kolmogorov-Smirnov test. The datasets taken for comparison were the 14 first day PT values for individuals tracked for only three days total, whilst the intra-individual variability considered was the six individuals tracked for a total of 6 days. Six separate intra-individual variabilities were therefore compared against inter-individual variability distribution (n = 14). Intra-individual data from individuals where the number of tracked days was only three was not considered, as the authors stated this sample size is too small to either 'bootstrap' or establish a probability distribution.

Four out of six individuals were tracked for a total of six daytime periods and their distribution of PT was found to be equivalent to the inter-individual PT dataset of 14 individuals on their first day of observation. As such it was concluded by the authors that intra-individual PT data from these four pigeons could be pooled with the 14 first day PT values from individuals only tracked for a three-day period. However for the other two individuals tracked for 6 days (reported as pigeon number 2 and 5) intra-variability was shown to be significantly different (Kolmogorov-Smirnov test, $P < 0.05$) to the variability between the 14 individuals considered for inter-bird variability. Therefore the PT data from birds 2 and 5 was annexed from the other individuals, to be considered separately (described below) in the Monte Carlo simulation. Presented in Table 2 are the example datasets for comparison of inter- and intra-individual variability

Table 2: Example datasets for comparison of inter- and intra-individual variability

	PT value for stubble field of tracking session (full-day radiotracking) number					
Woodpigeon individual	1	2	3	4	5	6
1	0.546*	—	—	—	—	—
2	0.054**	0.465**	0.110**	0.211**	0.000**	0.000**
3	0.335**	0.603**	0.254**	0.000**	0.000**	0.000**
4	0.486*	—	—	—	—	—
5	0.000**	0.000**	0.119**	0.000**	0.000**	0.000**
6	0.374**	0.052**	0.584**	0.719**	0.158**	0.541**
7	0.175*	—	—	—	—	—
8	1.000**	0.526**	0.967**	0.444**	0.429**	0.435**
9	0.933*	—	—	—	—	—
10	0.478*	—	—	—	—	—
11	0.497*	—	—	—	—	—
12	0.513*	—	—	—	—	—
13	0.118*	—	—	—	—	—
14	0.452*	—	—	—	—	—
15	0.447**	1.000**	0.923**	0.438**	0.542**	0.487**
16	0.140*	—	—	—	—	—
17	0.150*	—	—	—	—	—
18	0.399*	—	—	—	—	—
19	0.778*	—	—	—	—	—
20	0.366*	—	—	—	—	—

*Dataset representing inter-individual variability.
**Dataset for intra-individual variability.
PT = portion of diet obtained from a treated area.

Once the terms of pooling PT data were defined by the authors, for each Monte Carlo individual a random number from 1-20 was drawn, corresponding to an individual bird from the empirical dataset. If Bird number 2 or 5 was drawn (where intra-individual variability was established as not comparable to inter-individual variability) then the subsequent Monte Carlo individual was modelled using only empirical PT data from that individual. If however the drawn number corresponded to a bird other than 2 or 5, then the subsequent modelled individual drew from the empirical data of tracking session 1 (all individuals except 2 and 5) and all other tracking occasions for individuals tracked for six sessions (other than birds 2 or 5). As such the empirical datasets used to model the Monte-Carlo individuals (n = 1000) were as follows:

- Bird number drawn = 2: Only PT data from bird 2 were used to model the subsequent 21-days of PT behaviour for the Monte Carlo individual (so n = 6)
- Bird number drawn = 5: Only PT data from bird 5 were used to model the subsequent 21-days of PT behaviour for the Monte Carlo individual (so n = 6)
- Bird number drawn = 1, 3, 4, 6-20: PT data from session 1 (bird 1, 3, 4, 6-20) and sessions 2-6 for individuals 3, 6, 8, 15) used to model the subsequent 21-days of PT behaviour for the Monte Carlo individual (so n = 38)

This means that some empirical data was not relied on at all to model Monte Carlo individual bird PT behaviour: Sessions 2 and 3 for those birds (n= 14) tracked for only three days in total in the study, totalling 28 days of PT results.

To model each individual 21 empirical data points were randomly selected from the above described pools and then an arithmetic mean PT for the individual calculated. The period of 21-days was selected by the authors to correspond to the arbitrary period assumed for long-term exposure duration in the current EFSA bird and mammal risk assessment scheme. As a final step, the mean PT values for the Monte Carlo individuals (n = 1000) were plotted as a distribution and the 90th Percentile Mean PT value calculated = 0.46. However, with bootstrapping applied to the field data this was recalculated to be 0.53.

Appendix 3

Table1: Potentially foraging times per tracking session and trapping date and ring number of each woodpigeon

Wood pigeon	BTO Ring number	Trapping Date 2003	Tracking Date 2003	Session	potentially foraging time on stubble fields (hh:mm:ss)	potentially foraging time in other habitats (hh:mm:ss)	time pigeons were recorded with other behaviours (hh:mm:ss)
2b	FV86606	29 Aug	05 Oct	1	01:26:05	01:26:15	21:07:40
2b			06 Oct	2	01:10:53	02:08:53	20:40:14
2b			07 Oct	3	01:41:46	00:00:00	22:18:14
3c	FV86607	01 Sep	18 Sep	1	00:24:02	06:58:52	16:37:06
3c			19 Sep	2	00:59:39	01:08:36	21:51:45
3c			20 Sep	3	00:28:47	03:52:59	19:38:14
3c			22 Oct	4	00:09:42	00:36:12	23:14:06
3c			23 Oct	5	00:00:00	03:04:55	20:55:05
3c			24 Oct	6	00:00:00	00:48:10	23:11:50
4d	FV86608	01 Sep	22 Sep	1	01:03:01	02:04:49	20:52:10
4d			23 Sep	2	01:56:08	01:16:24	20:47:28
4d			24 Sep	3	01:09:13	03:23:30	19:27:17
4d			05 Nov	4	00:00:00	02:20:15	21:39:45
4d			06 Nov	5	00:00:00	02:21:12	21:38:48
4d			07 Nov	6	00:00:00	01:25:04	22:34:56
5e	FV86609	02 Sep	19 Sep	1	01:18:10	01:22:50	21:19:00
5e			20 Sep	2	01:45:56	01:03:17	21:10:47
5e			21 Sep	3	01:56:51	07:01:40	15:01:29
6f	FV86610	04 Sep	22 Sep	1	00:00:00	04:26:22	19:33:38
6f			23 Sep	2	00:00:00	05:12:18	18:47:42
6f			24 Sep	3	00:23:08	02:50:47	20:46:05
6f			09 Nov	4	00:00:00	03:34:42	20:24:18
6f			10 Nov	5	00:00:00	03:54:48	20:05:12
6f			11 Nov	6	00:00:00	02:44:50	21:15:10
7g	FV86990	27 Aug	26 Sep	1	00:45:27	01:16:09	21:58:24

Wood pigeon	BTO Ring number	Trapping Date 2003	Tracking Date 2003	Session	potentially foraging time on stubble fields (hh:mm:ss)	potentially foraging time in other habitats (hh:mm:ss)	time pigeons were recorded with other behaviours (hh:mm:ss)
7g			27 Sep	2	00:22:16	06:44:05	16:53:39
7g			28 Sep	3	00:52:24	00:37:22	22:30:14
7g			01 Nov	4	01:55:36	00:45:06	21:19:18
7g			02 Nov	5	00:44:57	03:59:09	19:15:54
7g			03 Nov	6	00:41:47	00:35:27	22:42:46
8h	FV86844	04 Sep	26 Sep	1	00:50:33	03:58:56	19:10:31
8h			27 Sep	2	02:13:05	06:13:52	15:33:03
8h			28 Sep	3	01:55:35	02:05:51	19:58:34
9i	FV86845	09 Sep	30 Sep	1	01:45:41	00:00:00	22:14:19
9i			01 Oct	2	00:43:03	00:38:49	22:38:08
9i			02 Oct	3	01:03:55	00:02:12	22:53:53
9i			22 Oct	4	00:48:55	01:01:19	22:09:46
9i			23 Oct	5	00:32:08	00:42:41	22:45:11
9i			24 Oct	6	01:11:17	01:32:38	21:16:05
10j	FV86846	09 Sep	30 Sep	1	04:22:59	00:18:51	19:18:10
10j			01 Oct	2	01:38:54	01:56:26	20:24:40
10j			02 Oct	3	00:52:23	06:49:26	16:18:11
11k	FV86847	11 Sep	05 Oct	1	01:40:19	01:49:37	20:30:04
11k			06 Oct	2	00:38:30	04:59:46	18:21:44
11k			07 Oct	3	01:01:41	06:19:16	16:39:03
12l	FV86848	11 Sep	09 Oct	1	03:28:26	03:30:44	17:00:50
12l			10 Oct	2	03:31:48	00:54:49	19:33:23
12l			11 Oct	3	00:57:47	00:51:09	22:11:04
14n	FV86850	11 Sep	09 Oct	1	00:31:52	00:30:18	22:57:50
14n			10 Oct	2	01:15:05	00:00:00	22:44:55
14n			11 Oct	3	02:01:17	00:49:57	21:08:46
15o	FV86851	14 Sep	17 Oct	1	00:46:42	05:50:31	17:22:47
15o			18 Oct	2	01:42:27	03:43:19	18:34:14

Wood pigeon	BTO Ring number	Trapping Date 2003	Tracking Date 2003	Session	potentially foraging time on stubble fields (hh:mm:ss)	potentially foraging time in other habitats (hh:mm:ss)	time pigeons were recorded with other behaviours (hh:mm:ss)
15o			19 Oct	3	01:38:38	05:25:23	16:55:59
16p	FV86852	14 Sep	13 Oct	1	01:22:17	01:39:35	20:58:08
16p			14 Oct	2	00:00:00	02:46:12	21:13:48
16p			15 Oct	3	00:28:14	04:07:21	19:24:25
17q	FV86853	14 Sep	13 Oct	1	00:34:46	00:42:57	22:42:17
17q			14 Oct	2	00:35:27	00:00:00	23:24:33
17q			15 Oct	3	01:42:05	00:08:32	22:09:23
17q			01 Nov	4	01:42:41	02:11:57	20:05:22
17q			02 Nov	5	01:27:21	01:13:47	21:18:52
17q			03 Nov	6	01:56:28	02:02:51	20:00:41
18r	FV86854	14 Sep	17 Oct	1	00:14:42	01:30:17	22:15:01
18r			18 Oct	2	00:00:00	01:17:23	22:42:37
18r			19 Oct	3	00:00:00	00:53:56	23:06:04
19s	FV86856	20 Sep	05 Nov	1	00:15:15	01:26:32	22:18:13
19s			06 Nov	2	00:00:00	00:58:31	23:01:29
19s			07 Nov	3	01:02:10	05:00:53	17:56:57
20t	FV86857	20 Sep	27 Oct	1	02:03:53	03:06:44	18:49:23
20t			28 Oct	2	02:32:24	01:08:11	20:19:25
20t			29 Oct	3	04:03:24	00:19:59	19:36:37
21u	FV86861	20 Sep	27 Oct	1	02:19:42	00:39:45	21:00:33
21u			28 Oct	2	04:23:48	00:36:41	18:59:31
21u			29 Oct	3	02:22:39	01:46:40	19:50:41
23w	FV86858	20 Sep	09 Nov	1	01:03:27	01:49:47	21:06:46
23w			10 Nov	2	00:00:00	03:23:59	20:36:01
23w			11 Nov	3	00:09:09	02:03:47	21:47:04