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Dermal exposure of bystanders and residents to direct spray drift in low crops during pesticide application

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ABSTRACT

A database was compiled with field measurement studies which were conducted by CropLife Europe (CLE) member companies between 2011 and 2019 to refine product-specific bystander and resident risk assessments and studies previously used to develop and test BREAM and BROWSE models. Bayesian analysis of the database suggests that the most important variables influencing drift are drift reduction, boom height, wind speed, mannequin height, distance downwind, crop class and formulation class. A comparison between BREAM 2 predictions and field measurements of potential bystander exposure have shown that the level of conservatism in the model is satisfactory and is therefore the most appropriate model currently available for risk assessment for bystanders and residents. Comparing spray drift values as median, 75th and 95th percentiles derived from the CLE data show that current EFSA guidance values significantly overestimate bystander/resident exposure.

1. Introduction

The original BREAM (Bystander and Resident Exposure Assessment Model) model (Kennedy et al., 2012) for bystander and resident exposure to spray drift from boom sprayers was incorporated into the European Food Safety Authority (EFSA) guidance for determining non-dietary exposures of humans to plant protection products in 2014 and subsequently in revised guidance in 2022 (EFSA, 2014, 2022). BREAM is a mechanistic model that predicts airborne spray and ground deposits, with an empirical component that relates airborne spray to deposits on the human body, from which dermal exposure can be calculated. The mechanistic component is based on the Silsoe Spray Drift Model (Butler Ellis et al., 2010), which is a particle-tracking model that predicts the movement of individual droplets released from a sprayer. However, instead of incorporating this model directly into BREAM, emulators were used instead which capture the main model behaviour and can be run very rapidly. The empirical component was based on bystander exposure data derived from two sources: Butler Ellis et al. (2010) and Glass et al. (2002). These were combined into a calculator which runs the algorithms multiple times, sampling inputs from distributions in order to produce a distribution of outputs (Kennedy et al., 2012). A further development of this approach was incorporated into the BROWSE (Bystanders, Residents, Operators and WorkerS Exposure models for plant protection products) model (Butler Ellis et al., 2017a) which included improved emulators and additional nozzles.

A revised version of the original BREAM model, BREAM 2, was subsequently produced (Butler Ellis et al., 2018) with improvements to the empirical component relating predicted airborne spray to dermal exposure. This replaced the field data with an empirical curve derived from specific experiments conducted in a wind tunnel, providing an improved description of the natural variability that occurs when measuring exposure to spray drift. BREAM 2 is, therefore, independent of all bystander exposure data obtained in the field.

The original BREAM was compared with the available field data (Kennedy et al., 2012) and the bystander exposure to spray drift component of BROWSE was compared with the same data set (Butler Ellis et al., 2017b). BREAM 2 was also compared with these data and showed that the prediction of potential exposure was improved

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compared with BREAM (Butler Ellis et al., 2018).

Since the development of BREAM, BREAM 2, and BROWSE models, new data were generated from bystander exposure studies conducted under real field conditions by CropLife Europe (CLE) companies in order to support plant protection product (PPP) registrations. This was prompted in part because BREAM, as implemented into the guidance document (EFSA, 2014), was over-conservative which was also the reason for the development of BREAM 2. These new field data have been collated into a database, based on an Excel spreadsheet, which was then used for statistical analysis and evaluation of the performance of the bystander exposure model BREAM 2.

2. Materials and methods

2.1. Development of the database

A database was compiled from 15 GLP (Good Laboratory Practice) studies which were conducted by CLE member companies between 2011 and 2019 to refine product-specific bystander and resident risk assessments. Four studies previously used to develop and test BREAM and BROWSE models (Butler Ellis et al., 2010; Glass et al., 2010) were also included. The final database consisted of 514 exposure values.

2.2. Locations and application details

The studies were conducted in different locations across Europe under field conditions. The details of the main application parameters (e.g. crop type, application method, nozzle type), conditions (i.e. wind speed), and sampling setup (i.e. replicates, distances) of each trial are summarized in Supplementary Material 1.

2.3. Sampling setup and measurements

A total of 514 replicates were used in the studies, with 292 adult and 222 child mannequins (adults body height 1.7-1.9 m and children 0.96-1 m). Mannequins were always positioned facing the treated area at various distances (depending on the study 1.25-13.25 m) downwind from the zero-metre position. For a set-up with multiple rows of mannequins, to reduce possible interference of the drift, mannequins in the second row were off-set by 1 m from the mannequins in the first row, and the same for the third row.

In 15 CLE studies, dermal exposure was determined using whole body dosimetry according to the approach described in OECD Test Guideline No. 9 (OECD, 1997) and OPPTS 875.1100 (US EPA, 1996). The test system comprised the dermal exposure sampling media worn by adult and child sized mannequins. Inner dosimeters consisted of full-length 100% cotton underwear garments (long-sleeved vest and long johns) and a head sleeve. Outer dosimeters consisted of 100% cotton t-shirts and shorts or 100% t-shirt and 65% polyester/35% cotton shorts to represent a minimal clothing scenario for bystanders and residents. More details are summarized in Supplementary Material 1. In four BREAM studies, the dosimeters were Sontara (impermeable) coveralls and cotton gloves, Tyvek coveralls, or paper overalls, and only potential exposure was measured.

In total, 10 active substances or tracer dyes were analysed from application of in-use dilutions of 6 different formulation types. The active substances or tracer dyes used in these studies were merely surrogate analytes that were measured on dosimeters. This follows the principle established by US EPA in 1996 in OPPTS 875.1000 (US EPA, 1996).

The potential and actual exposure data were reported as a quantity of spray liquid based on the known concentration of active substance.

2.4. Environmental conditions

All 15 CLE studies captured wind speed, temperature and relative humidity measurements for the sampling periods. Wind speed was measured 2 m above ground. The overall range of wind speed across all trials was between 2.1 and 8.18 m/s; temperature was 7.4–31 °C; relative humidity was 36–96.6%. More details are summarized in Supplementary Material 1. There were no rainfall events during spray application in any of the studies.

2.5. Other studies included in the database

The database also included studies undertaken as part of the BREAM project (Butler Ellis et al., 2010) and another study commissioned by the UK regulator (Glass et al., 2002). These data had been used in the development of the original BREAM model and had been used to validate the BREAM model (Kennedy et al., 2012).

2.6. Data processing

These data were then processed further to enable a meaningful statistical analysis to be conducted and to provide input data for running BREAM 2. This involved:

- Nozzle categories: Grouping the nozzle/pressure combination for each trial into three categories
- Downwind distance: Adjusting distance downwind to be relative to a common 'zero' value, i.e. location of the end nozzle
- Crop class: Grouping crops into two categories
- Formulation class: Grouping formulation types into three categories
- Sprayer speed: Checking nozzle type, pressure, sprayer speed and applied volume for consistency. Expert judgement was used to estimate actual values in some cases.

2.7. Nozzle categories

The nozzle design and size and the operating pressure together define the droplet size distribution produced by the sprayer. A wide range of nozzle/pressure combinations, and therefore potentially a wide range of droplet size distributions, were used in the field trials. BREAM 2 allows inputs relating to only a single 'reference' spray and 50%, 75% and 90% drift reduction (DR). The BREAM reference spray is a conventional 110° flat fan nozzle, '03' size, operated at 3.0 bar. The Teejet 11003 TP nozzle defines the boundary between the 'fine' and 'medium' quality sprays in the international standard for spray classification (International Standards Organisation, 2018) and so effectively provides the most drift that can be achieved with a 'medium' quality spray. In the UK, the majority of product labels specify a medium quality spray and therefore this nozzle/pressure was seen as a reasonable worst case for the UK.

Following initial statistical analysis, all nozzles that did not have a DR class and were known not to be DR nozzles were allocated to the 'reference' category, recognising that this will contribute to a wider variation in the data relating to 'reference' sprays than if a single nozzle/pressure combination was included. Other nozzle/pressures were allocated 50% DR and 75% DR. The DR class was determined from a combination of published DR values, known data, or expert judgement.

2.8. Downwind distance

Different field studies consider different 'zero distance' locations and therefore all data has to be adjusted to be on the same basis. BREAM 2 takes zero distance as the location of the most downwind nozzle, whereas CLE field studies applied edge of the treated field, 0.25 m from the most downwind nozzle or the most downwind nozzle, as the zero value. In order to run BREAM 2, all distances were adjusted to distance from the most downwind nozzle.

2.9. Crop class

The database recorded eight different crop types: grass, oilseed rape (OSR), pre-emergence, spring barley, sugar beet, wheat, winter barley and winter wheat (i.e., all crops between BBCH stages 18-65 and height 25-140 cm, and soil/short vegetation <15 cm).

Following the initial analysis, all crop types were grouped in two categories, ‘crop’ or ‘soil/short vegetation’, effectively testing the presence or absence of crop on exposure.

2.10. Formulation class

Six different formulation types were recorded in the database: aqueous solution, emulsion concentrate (EC), oil dispersion (OD), suspension concentrate (SC), soluble liquid (SL), and water-dispersible granules (WG) (CropLife International, 2022). Note that the aqueous solution relates to tracer dye rather than a formulated PPP.

Formulation affects spray drift by changing the spray break-up mechanism, changing droplet size and velocity (Butler Ellis and Tuck, 1997; Butler Ellis and Bradley, 2002). The properties of the undiluted product are unlikely to be important factors in determining this, rather the properties of the diluted tank mix (although clearly these are related). Three different tank mix types have been identified previously as important: ‘emulsions’ (dispersed liquid particles), ‘suspensions’ (dispersed solid particles) and homogeneous liquids such as ‘solutions’. The six formulation types were therefore grouped in three formulation classes, based on the nature of the diluted tank mix, i.e. emulsion, suspension and solution.

2.11. Sprayer speed

Several trials had a reported speed, nozzle size, pressure and applied volume that were considered inconsistent. Authors have been unable to establish accurate values for these cases, but based on expert judgement, it seems likely that the sprayer speed was the greatest source of inaccuracy, as it may have been calculated from the total duration of the spraying operation, which would take account of time spent turning between passes. An alternative sprayer speed, to reflect the speed during spraying, was instead deduced from the stated volume, nozzle and pressure.

2.12. Bayesian analysis of exposure data

As an alternative to the mechanistic BREAM 2 model, a statistical model was fitted using the 514 records. The model predicts log10-transformed potential dermal exposure as a function of other measured (predictor) variables. Bayesian inference was used to allow for uncertainty about the parameter values, and their effects on the predicted exposure, to be quantified.

Relevant predictor variables were selected using a combination of expert opinion and statistical modelling steps:

- Pre-selection of database variables that could potentially influence spray drift or exposure, based on expert opinion. At this stage, variables with many missing entries were excluded.
- Exploratory data analysis to identify potentially influential input variables. Data plots were reviewed to decide whether the data design might be leading to misleading interpretations. As the study combined data from multiple observational studies, it was important to assess the potential for any bias due to unbalanced design.
- Based on these initial assessments, alternative plausible models were fitted to the 514 measured data records and assessed for goodness of fit when predicting (log10-transformed) potential dermal exposure.
- Parameters for which the 95% posterior credible interval included zero were excluded. Remaining parameters were kept in the model, unless the estimated effect was believed to be implausible and could be a result of unbalanced data design or confounding effects.

This was an iterative process, in which the model steps were repeated following feedback of intermediate results or corrections to errors identified in the data.

Weak prior distributions were assigned to statistical model parameters to reflect a lack of information prior to observing the data. The posterior distribution quantifies the estimated values and remaining uncertainty in each parameter, after updating using information from the measured data. Simulations from these distributions can be used to predict exposure under different conditions or to compare against observations for model checking.

The models were fit using the R software (R Core Team, 2022) with R package rstanarm (Goodrich et al., 2023). A standard linear model was assumed with residual errors assumed to be normally distributed with mean 0 and unknown standard deviation. For linear coefficients in the model μ_i, the following weak prior distributions were assigned:

$\mu_i \sim N(0, 3^2)$ for all continuous variables after subtracting the column mean and dividing by the column standard deviation to standardise each variable, and $\sigma \sim \mathrm{Exp}(rate = 10)$ for the standard deviation of the residual error term. A formula is used to specify the model form (expected mean, as a function of the predictor variables), which in our case is a linear function of the selected parameters, for example:

log10pot_derm_ml ~ 1 + Nozzle_category + Boom_height_above_crop + Mannequin_height + Distance_m_from_end_of_spray_boom + Wind_speed_ms + Short_crop_or_soil + Formulation_class

The “1” indicates the overall model estimate (intercept). Additional interaction terms were included in the final model to represent the extra effects of wind speed coupled with specific DR nozzle types.

2.13. Comparison of exposure data with BREAM 2 predictions

The BREAM 2 was run for each of the experimental data points to enable comparison between predicted and measured potential dermal exposure. The inputs for BREAM 2 were taken from the database:

- Nozzle category (reference, 50% DR, 75% DR)
- Number of nozzles (2 × width of treated area)
- Boom height above crop (m)
- Sprayer speed (km/h)
- Population (Child or Adult)
- Distance downwind (measured from the end nozzle) (m)
- Mean wind speed at 2 m above ground (m/s)

Note that formulation type and crop are variables that are not currently included in BREAM 2.

Two comparisons were conducted: (i) BREAM 2 predictions were compared with only new data that had not been used in the development of any of the BREAM models or included in previous validation exercises, i.e. data from the four BREAM trials were excluded. (ii) Then the analysis was repeated with the full dataset (see under Development of the database).

3. Results

3.1. Bayesian analysis of exposure data

The variables that were considered to have a potential non-zero influence on the exposure, from the selection available in the database, are shown in Table 1.

Fig. 1 shows the fitted parameters of the final selected model and 90% uncertainty intervals. For categorical variables it is not necessary to include a parameter for all levels. The combined effect of the default categorical settings (reference nozzle and emulsion formulation) is

Table 1
Variables in the database considered as potential predictor variables. In the model, bystander population was instead represented using the continuous variable mannequin height.

Variable	Unit	Values
Formulation class		Solution, Suspension, Emulsion
Crop class		Crop, soil/short vegetation
Crop/vegetation height	cm	10 – 140
Water volume	L/ha	75 - 205.8
Nozzle category		Reference, 50% DR, 75% DR
Width of treated area	m	12 – 360
Boom height above crop	m	0.5 - 1.1
Speed	km/h	5.29 – 16
Population		Child, Adult

quantified within the intercept term. Interaction terms for wind speed and DR nozzle category were introduced to account for the fact that the wind speed effect is believed to be reduced when DR nozzles are used. The results show that these interaction terms are negative, which is consistent with this assumption. Considered as a continuous predictor variable, crop height was not found to have a significant effect on exposure, given these data. The simpler 2-state variable crop class was found to have an impact. In the exploratory data analysis phase, it was clear that crop height was highly correlated with crop type. This, together with the potential for multi-collinearity between crop height and other features caused by the unbalanced design, resulted in the crop height being excluded as a separate fitted predictor.

The parameter estimates that are positive are those that have an increasing effect on exposure for larger values. Increasing boom height above the crop, wind speed and mannequin height all lead to higher potential exposures as expected. The models also suggest that having bare soil or short vegetation increases exposure, as does the use of a solution formulation (compared to the emulsion formulation). Negative effects, leading to reduced exposure estimates are associated with DR nozzles, use of suspension formulation and increasing distance from the boom.

Water volume and width of treated area were excluded because their estimated effects were found to be the opposite of what would be considered plausible. For example, based on a purely statistical model fit criteria the size of treated field is classed as having an important influence on exposure but with a negative effect. This would imply that a wider treated area leads to lower exposure, which is not considered plausible and therefore was not retained as a parameter. Implausible effects can arise in the model fit due to an unbalanced field study design. In this case the study data could be improved if observations with the narrowest/widest treated area included a more diverse range of conditions to identify the true driver of exposures.

3.2. Comparison of new exposure data with BREAM 2 predictions

The new CLE-generated observed data are compared against the BREAM 2 median, 75th and 95th percentile estimates in Fig. 2–4. BREAM 2 uses Monte Carlo simulation to quantify the impact that real variability in the input parameters produces in the exposure predictions. The model generates a large sample of outputs to represent the distribution of true exposures and the median, 75th and 95th percentiles are presented to predict either a typical exposure or more extreme exposures. Points above the diagonal 1:1 line are overestimates. These show that there are particular subsets that are more likely to be overpredicted by BREAM 2. In particular, the suspension formulation cases are always overpredicted. Emulsion formulations and cereal crops are the scenarios more likely to have a mix of under- and over-prediction compared to others. To check against the target levels of conservatism, summary percentages of new data cases for which the BREAM 2 model estimates are higher are summarized in Table 2.

For an accurate model one would expect 50% of data points to be less than the median, 75% less than the 75th percentile and 95% less than the 95th percentile. Overall, BREAM 2 is overly conservative for these cases when predicting the median and 75th percentile exposures and the 95th percentile estimate is on target (95%).

3.3. Comparison of all exposure data with BREAM 2 predictions

When comparing BREAM 2 predictions with the full set of observed data, which includes the data used in calibrating and validating BREAM 2, we see that BREAM 2 is able to accurately predict for a wider range of scenarios (Fig. 5–8). The solution cases and the soil/short vegetation cases with relatively high exposure values have a more even distribution of over-predicted and under-predicted cases compared with the predictions of the new data seen in Fig. 2–4. To check against the target levels of conservatism, summary percentages of all data cases for which the BREAM 2 model estimates are higher are summarized in Table 3.

The collection of errors from the BREAM 2 median estimates, calculated at the same complete set of observations, has variance 0.287 on log10 scale. The 514 complete observations alone have variance 0.566 on the log10 scale. Therefore, the proportion of total variation explained by the BREAM 2 median model is (0.566 - 0.287)/0.566 which is approximately 49%. We know that the median only captures part of the true variation in the measured values. By using the Monte Carlo uncertainty analysis and reporting 75th or 95th percentiles, the additional variation due to random variations in conditions is approximated.

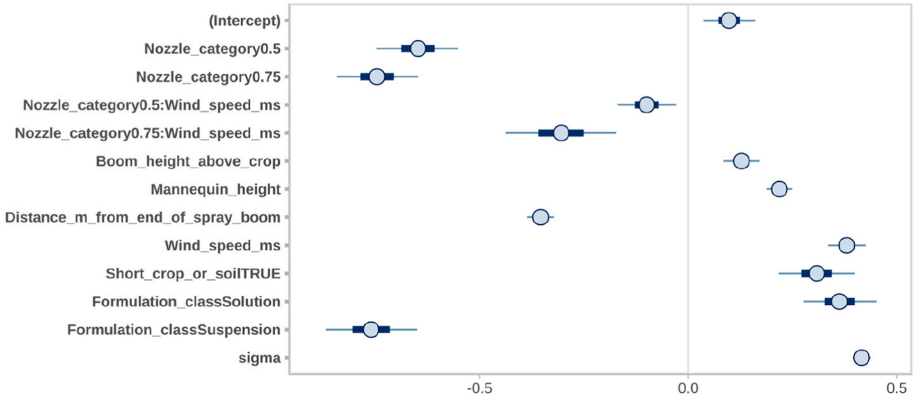

Fig. 1. Summary of distributions for fitted model parameters, in the Bayesian model that includes boom height and interaction terms for wind speed per nozzle type. Sigma is the standard deviation of the residual error term. Circles are median point estimates, horizontal bars cover the 50% and 90% probability intervals.

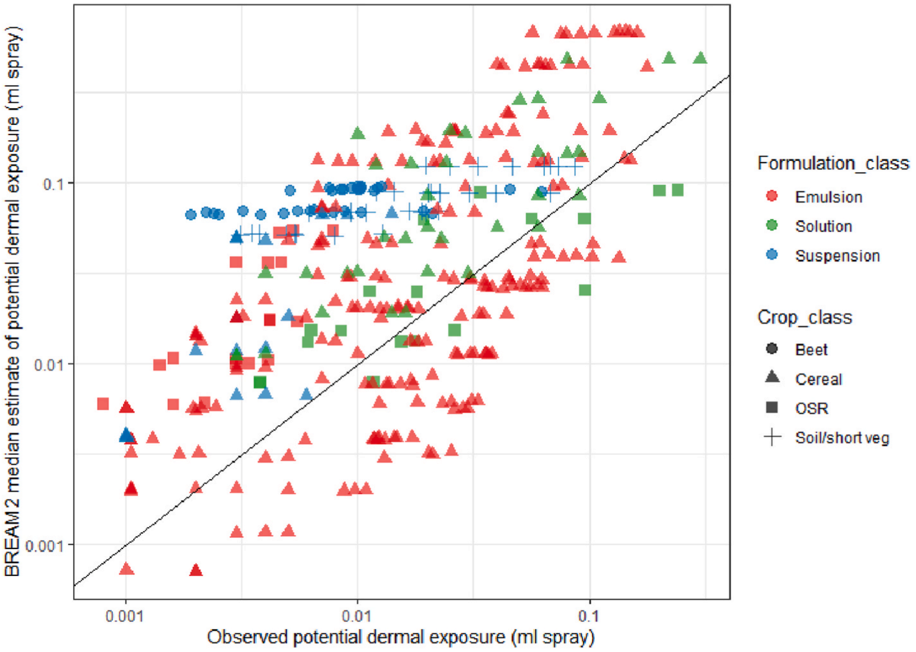

Fig. 2. Observed exposure values (new data) versus their BREAM 2 median estimates (potential dermal exposure, ml spray). Formulation classes are represented using different colours, while the 4 crop classes are represented using different shapes. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

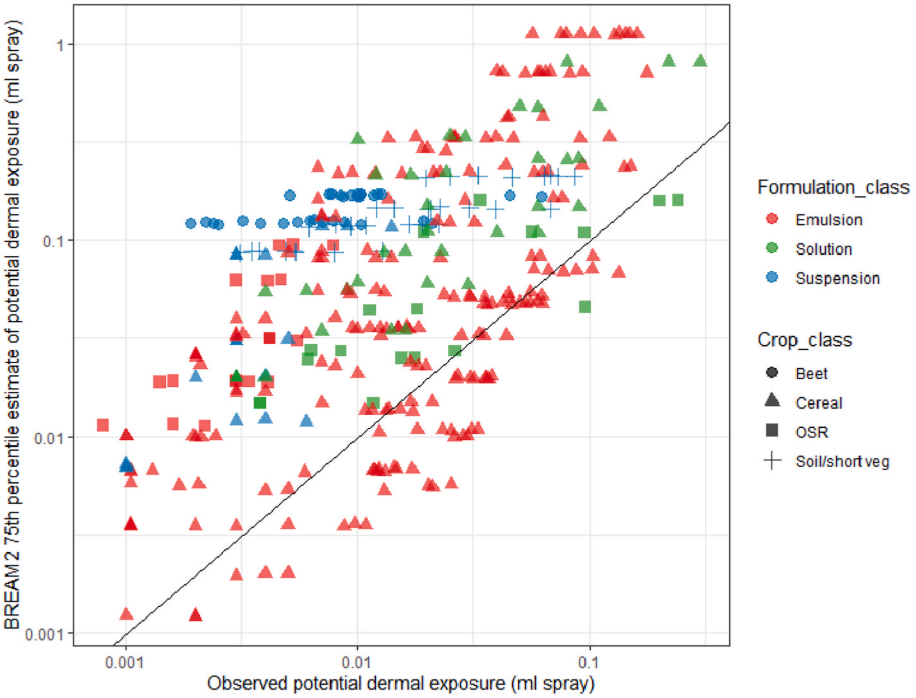

Fig. 3. Observed exposure values (new data) versus their BREAM 2 75th percentile estimates (potential dermal exposure, ml spray). Formulation classes are represented using different colours, while the 4 crop classes are represented using different shapes. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

3.4. *Empirical approach to exposure*

Considering data from 15 GLP field studies owned by CLE member companies, an empirical approach could be taken to derive spray drift exposure values expressed 'mL spray/person' for adult and child for multiple distances, as it is currently applied in EFSA, 2022. Tables 4–6 summarize the spray drift values for a 'reference', '50% DR, and '75% DR nozzle types, respectively, as described above and comparison with EFSA, 2022 values derived from BREAM.

Bayesian analysis of exposure data indicated a negative effect of distance, i.e., leading to reduced exposure estimates by increasing distance from the boom, therefore a simple grouping of distances has been summarized in Tables 4–6 (detailed information in Supplementary Material 1), considering the 3 nozzle classes separately. ANOVA analysis

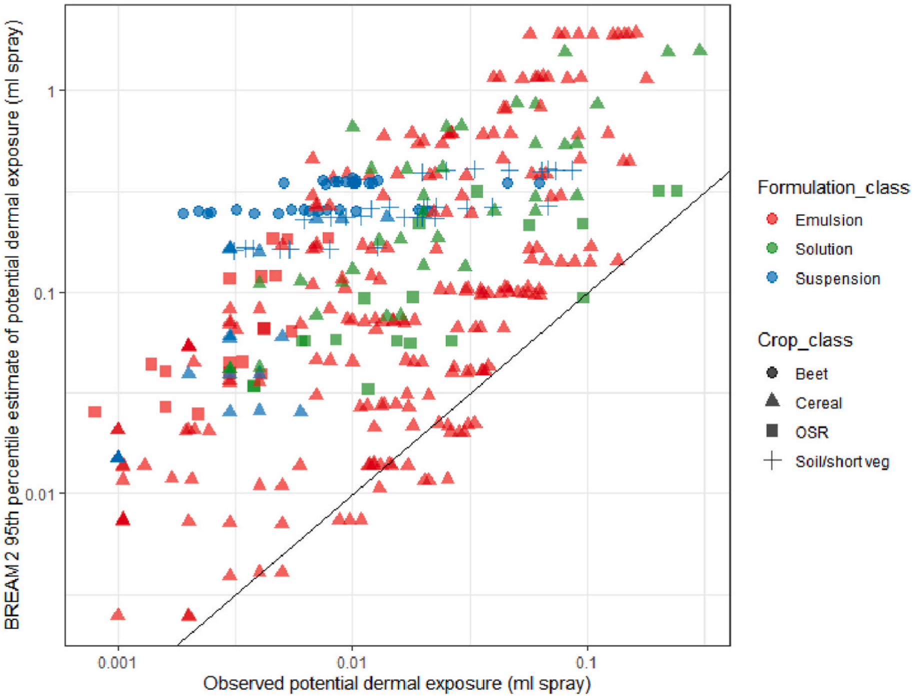

Fig. 4. Observed exposure values (new data) versus their BREAM 2 95th percentile estimates (potential dermal exposure, ml spray). Formulation classes are represented using different colours, while the 4 crop classes are represented using different shapes. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

Table 2

Summary percentages of new data cases for which the BREAM 2 model estimates are higher, to check against the target levels of conservatism. New data only (excluding measurements previously used to develop BREAM), N = 360.

Percentage of cases with BREAM 2 prediction exceeding observation		
Median BREAM 2	75th percentile BREAM 2	95th percentile BREAM 2
73	83	95

was performed independently for adult and child subpopulations, to test for significant differences between the means of spray drift values between distance groups. For ‘reference’ and ‘50% DR’ nozzle type each test shows a significant difference for both potential and actual exposure ($P < 0.05$). For ‘75% DR’ nozzle type no significant difference was observed for both adult and child and potential and actual exposure, however, both 50% and 75% DR’ nozzle types should be treated with caution due to limited number of datapoints (see Tables 5 and 6).

For ‘reference’ nozzle, the proposed spray drift values by EFSA, 2014, 2022 are 4.6-41 times higher than median, 75th and 95th percentile values in CLE data.

For ‘50% DR’ nozzle, the proposed spray drift values by EFSA, 2014, 2022 are 4.2-160 times higher than median, 75th and 95th percentile values in CLE data.

For ‘75% DR’ nozzle, the proposed spray drift values by EFSA, 2014, 2022 are 7.8-137 times higher than median, 75th and 95th percentile values in CLE data.

4. Discussion

The focus of this research was field studies conducted to refine product-specific bystander and resident risk assessments in low crops treated by ground-based boom sprayers. It was also focused on potential and actual dermal exposure (mL spray), since inhalation exposure for low crop spray applications is significantly lower than dermal exposure and thus a minor contributor to overall exposure. The same studies included in the current database have been reviewed in different context also previously in Kuster et al., 2021, addressing the performance of DR nozzles, initial comparisons with BREAM 2 and suggesting the higher protection by ordinary clothing than default assumptions by EFSA, 2014, 2022, and Felkers et al. (2023), addressing a detailed review of the protection by ordinary clothing improving the actual dermal exposure assessment.

Literature search for bystander dermal exposure studies in field crops did not reveal any published data using the same study setup with mannequins and measuring exposure expressed in mL spray/person. However, there have been several experiments measuring airborne drift (Wolters et al., 2008; van de Zande et al., 2017) or airborne drift and using a modified/limited setup with flat wood mannequins and only partial dosimeter T-shirt (Perriot et al., 2024), therefore relevant comparison cannot be made and such data in the public domain were not considered. Also, bystander spray drift data on high crops or drones have not been deemed relevant and therefore were not considered.

The main advantage of the Bayesian model is its ability to quantify the uncertainty of exposure predictions and of the individual parameter effects (see Fig. 1). The small uncertainty intervals indicate strong evidence of real effects. Potential weaknesses are that it requires prior information to be specified, and subjective decisions about the variables to include in the model. Expert opinion has been used for grouping nozzles and crop types into meaningful classes, for example. Weak prior information has been used for parameter distributions, to approximate an uninformative prior distribution and therefore avoid subjective bias. The model fitting will also be influenced by the unbalanced dataset including missing data. The possibility of errors caused by unbalanced or unrepresentative data settings were assessed during the exploratory analysis, and variables whose predicted effects were believed to be incorrectly estimated as important were excluded. However, this does not fully compensate for the unbalanced experimental design. To establish stronger conclusions related to crop type and formulation effects, it is recommended to collect experimental data with a more balanced set of application scenarios. Water volume and width of treated area were removed as variables from the Bayesian model because the data suggests an implausible relationship, with increasing water volume

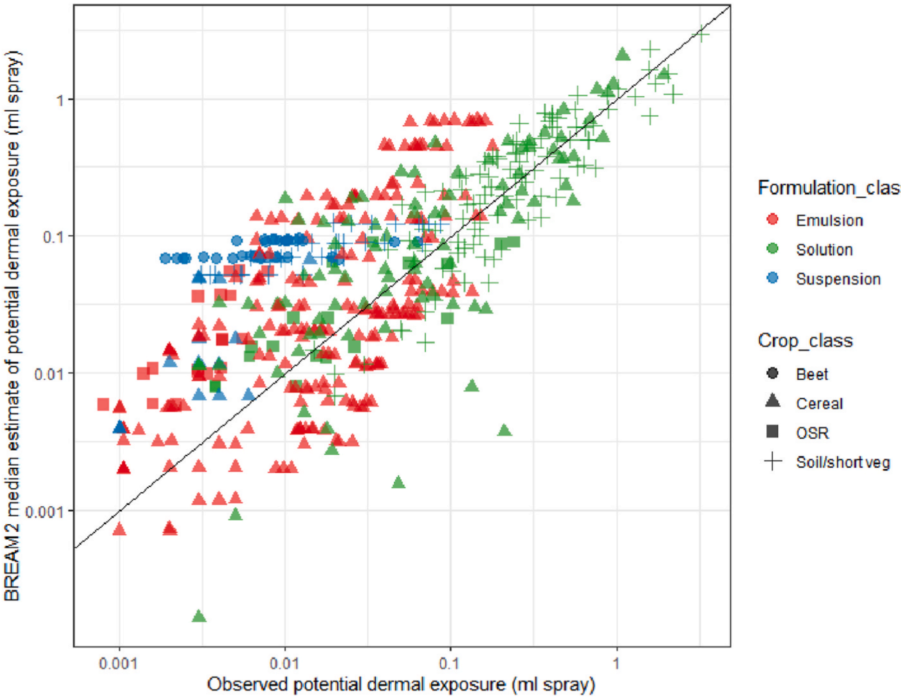

Fig. 5. Observed exposure values (all data) versus their BREAM 2 median estimates (potential dermal exposure, ml spray). Formulation classes are represented using different colours, while the 4 crop classes are represented using different shapes. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

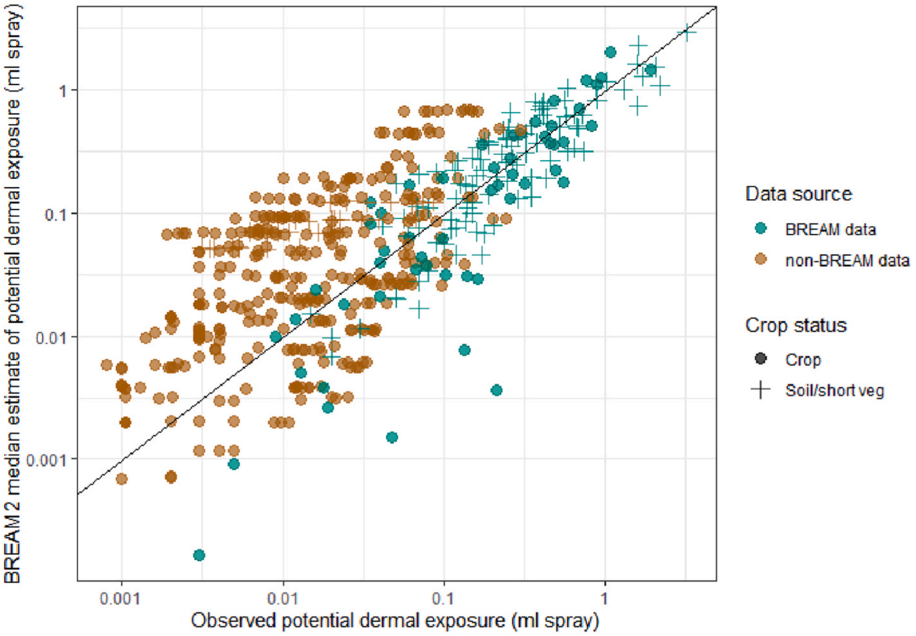

Fig. 6. Observed exposure values (all data) versus their BREAM 2 median estimates (potential dermal exposure, ml spray). The data values are identical to Fig. 5 but the colours differentiate the data used in building BREAM 2 versus independent data. All crop types other than soil/short vegetation are also shown as circles here. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

and increasing treated area both suggesting a reduction in exposure to spray liquid. This was likely to be as a result of imbalanced data, which covers too narrow a range of volumes and treated areas. This occurs because CLE trials, undertaken to provide regulatory data, aimed to match EFSA's defined application scenario (which has been adhered to for exposure studies by Member States despite a wider variation of spray parameters in real field conditions). In addition, the BREAM data included in the database had the smallest treated areas but were deliberately undertaken using high-drift conditions.

Some CLE studies, due to a lack of calibration data, may not have accurately reported application volume. Additionally, it should be noted that the measurements of volume and nozzle pressure may also be inappropriate, and a formal sprayer calibration exercise would have provided the necessary information. This is an essential part of a drift study and is required by the spray operator to ensure the required dose is achieved. The Bayesian data analysis was undertaken to identify

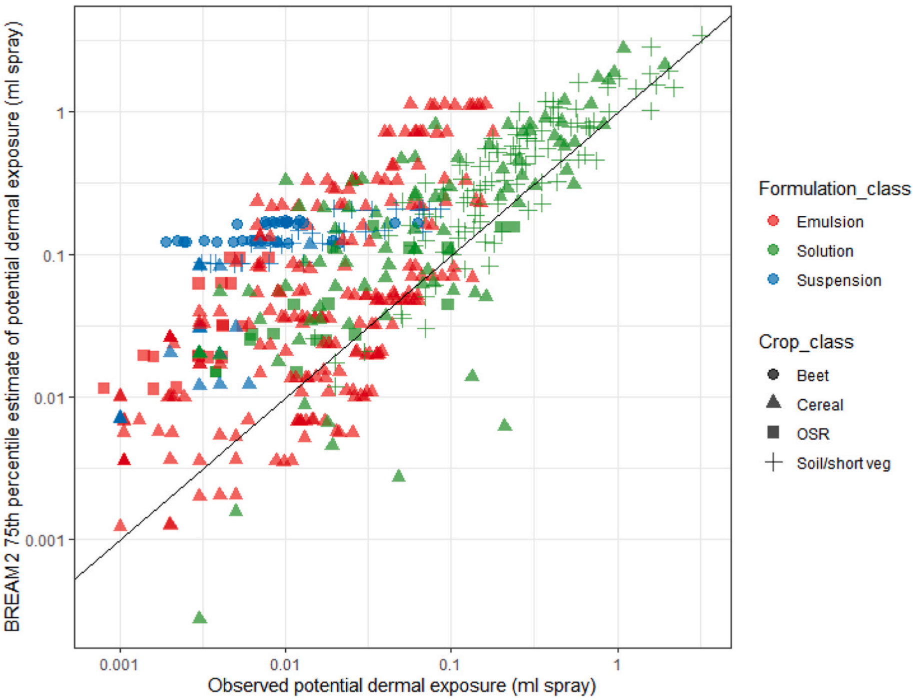

Fig. 7. Observed exposure values (all data) versus their BREAM 2 75th percentile estimates (potential dermal exposure, ml spray). Formulation classes are represented using different colours, while the 4 crop classes are represented using different shapes. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

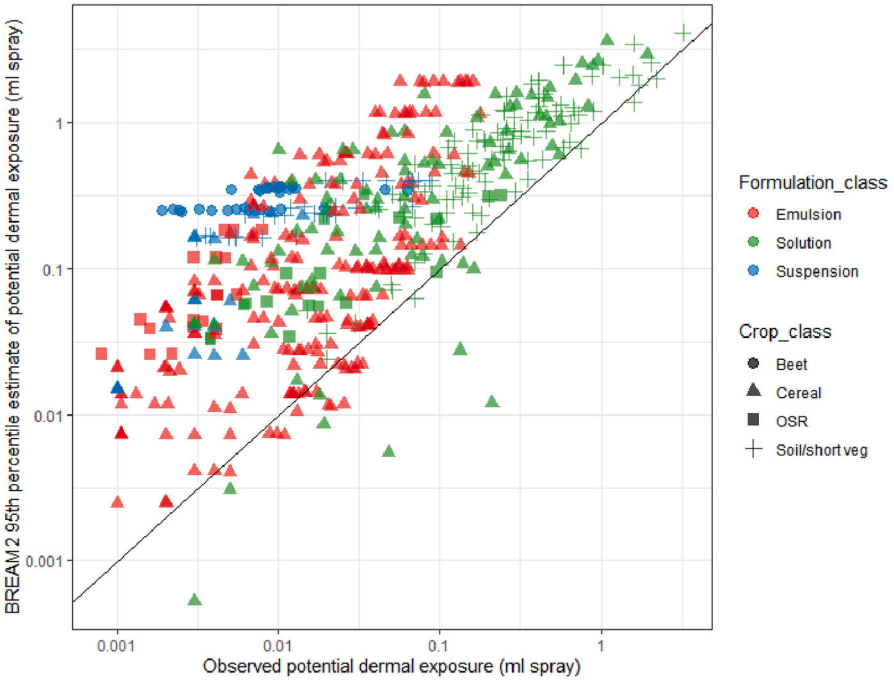

Fig. 8. Observed exposure values (all data) versus their BREAM 2 95th percentile estimates (potential dermal exposure, ml spray). Formulation classes are represented using different colours, while the 4 crop classes are represented using different shapes. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

whether the inclusion of further variables in the BREAM 2 model could be beneficial. This suggested that two variables – not currently included in BREAM 2 – could be relevant to exposure. Fig. 1 suggests that formulation type and the presence of crop are two that could be considered.

The underlying model on which BREAM 2 is based does include a crop (and this was included in BROWSE (Butler Ellis et al., 2017a, 2017b), which is a similar model to the original BREAM, and developed as part of a European Framework 7 project). Model input parameters are crop height and a droplet capture component. Droplet capture by vegetation needs to be tested and calibrated empirically, and insufficient data is currently available.

Table 3
Summary percentages of all data cases for which the BREAM 2 model estimates are higher, to check against the target levels of conservatism. All data included, N = 514. Highlighted in bold are cases where the percentage is below the target level.

Percentage of cases with BREAM 2 prediction exceeding observation		
Median BREAM 2	75th percentile BREAM 2	95th percentile BREAM 2
66	80	***94***

It is often assumed that drift is likely to increase with a crop presence (because of increased boom height) and this is reflected in BROWSE. Ground deposits of drift data from the Netherlands, suggests that this is the case whereas German data with cereals suggests the opposite is true (van de Zande et al., 2013). Our Bayesian analysis suggests the presence of a crop reduces exposures therefore short crop/bare soil remains the worst case. This may be because the majority of the crop data are with cereals. Further work to explore the impact of the presence of crop would be beneficial, since analyses show that boom height, wind speed

Table 4
Summary of CLE-generated spray drift values (mL spray/person) for a ‘reference’ nozzle type and comparison with EFSA, 2022 values derived from BREAM.

		EFSA, 2022, Adult	EFSA, 2022, Child	All crops, Adult	All crops, Child
Potential exposure	Distance, m	2	2	2-3.25	2-3.25
	Median	0.22	0.18	0.0445	0.0168
	Distance, m	**5**	**5**	**5.25–8.25**	**5.25–8.25**
	Median	0.12	0.12	0.0260	0.0123
	Distance, m	**10**	**10**	**10.25–13.25**	**10.25–13.25**
	Median	0.11	0.10	0.0130	0.0038
Actual exposure[a]	**Distance, m**	**2**	**2**	**2–3.25**	**2–3.25**
	Median	0.1804	0.1476	0.0239	0.0087
	Distance, m	**5**	**5**	**5.25–8.25**	**5.25–8.25**
	Median	0.0984	0.0984	0.0138	0.0060
	Distance, m	**10**	**10**	**10.25–13.25**	**10.25–13.25**
	Median	0.0902	0.082	0.0070	0.0020

[a] Actual exposure = Potential exposure x 0.82 (derived acc. to EFSA 2022).

Table 5
Summary of CLE-generated spray drift values (mL spray/person) for a ‘50% DR’ nozzle type and comparison with EFSA, 2022 values derived from BREAM[b].

		EFSA, 2022, Adult	EFSA, 2022, Child	All crops, Adult	All crops, Child
Potential exposure	Distance, m	2	2	2.25	2.25
	Median	0.11	0.09	0.0263	0.0162
	Distance, m	5	5	**5.25**	**5.25**
	Median	0.06	0.06	0.0045	0.0020
	Distance, m	**10**	**10**	**10.25**	**10.25**
	Median	0.055	0.05	0.0035	0.0015
Actual exposure[a]	**Distance, m**	**2**	**2**	**2.25**	**2.25**
	Median	0.0902	0.0738	0.0168	0.0095
	Distance, m	5	5	**5.25**	**5.25**
	Median	0.0492	0.0492	0.0030	0.0010
	Distance, m	**10**	**10**	**10.25**	**10.25**
	Median	0.0451	0.041	0.0020	0.0010

[a] Actual exposure = Potential exposure x 0.82 (derived acc. to EFSA 2022).
[b] Exposure for DR technology derived multiplying exposure value with 0.5 (acc. to EFSA 2022).

Table 6
Summary of CLE-generated spray drift values (mL spray/person) for a ‘75% DR’ nozzle type and comparison with EFSA, 2022 values derived from BREAM[b].

		EFSA, 2022, Adult	EFSA, 2022, Child	All crops, Adult	All crops, Child
Potential exposure	Distance, m	2	2	2.25-3.25	2.25-3.25
	Median	0.165	0.135	0.0126	0.0070
	Distance, m	**5**	**5**	**5.25–8.25**	**5.25–8.25**
	Median	0.09	0.09	0.0042	0.0030
	Distance, m	**10**	**10**	**13.25**	**13.25**
	Median	0.0825	0.08	0.0030	0.0016
Actual exposure[a]	**Distance, m**	**2**	**2**	**2.25–3.25**	**2.25–3.25**
	Median	0.1353	0.1107	0.0061	0.0040
	Distance, m	**5**	**5**	**5.25–8.25**	**5.25–8.25**
	Median	0.0738	0.0738	0.0032	0.0022
	Distance, m	**10**	**10**	**13.25**	**13.25**
	Median	0.06765	0.0615	0.0023	0.0010

[a] Actual exposure = Potential exposure x 0.82 (derived acc. to EFSA 2022).
[b] Exposure for DR technology derived multiplying exposure value with 0.75 (not acc. to EFSA 2022, but applying the same approach as for ‘50% DR’ nozzle type).

and crop status appeared to be jointly significant factors. However, due to these competing effects, it is recognised that a definitive conclusion about their relative impact cannot be drawn due to the unbalanced nature of the available data.

Formulation influences spray drift through its effect on droplet size and velocity. The droplet size and velocity used in BREAM 2 relate to the boundary between a fine and medium spray, and therefore represent the worst-case of drift for a medium quality spray, independent of any particular tank mix. It has long been known that different formulations can reduce drift, but to take advantage of this to implement formulation as a regulatory drift mitigation measure, it would require products to be used without tank mixing. However, recognising that moves towards precision application are likely to lead to more individual ‘prescriptions’, there may be a move away from multiple product tank-mixing in some circumstances.

The effect that an individual product has on drift could be included in a number of ways. It should be noted that the product cannot be considered independently of the nozzle: the effect on droplet size of a particular product depends on nozzle design. It cannot be assumed, either, that formulations can be put into classes where they all behave in the same way. There is evidence of common trends for soluble liquids and emulsions, but the magnitude of any effect is very variable, depending on co-formulants (Butler Ellis et al., 1999, 2001, 2016; Miller and Butler Ellis, 2000; Butler Ellis and Tuck, 2000).

Overall, considering the predicted outcomes of BREAM 2 against field data, it has been shown that the level of conservatism for all data is satisfactory, with 80% of measured data less than the 75th percentile and 94% less than the 95th percentile, making BREAM 2 the most appropriate model to predict spray drift to bystanders/residents in low crops. However, more field data would be valuable to evaluate whether the effect of some of the variables currently included in BREAM 2 is consistent with field conditions, e.g., nozzles with higher levels of drift reduction, a wider range of products and a wider range of application volumes. Further field data would also be valuable to expand BREAM 2 to include crop with wide range of structures and growth stages as another variable. The drift-reducing effect of individual products could be introduced into BREAM 2 through a simple adjustment factor, based on measurements of droplet size distribution. It has to be noted that the considered field studies already provide an element of worst-case, by using experimental protocols that were largely consistent with the international standard for field measurements of drift ISO 22866:2005 (International Standards Organisation, 2005). This ensures low wind direction variability, low levels of turbulence and no vegetation in the downwind sampling area, all of which would be expected to contribute to higher bystander exposures compared with realistic conditions.

An empirical approach taken to derive the spray drift values expressed as ‘mL spray/person’ for adult and child for multiple distances using only 15 GLP field studies owned by CLE member companies has to be treated with caution due to the unbalanced nature of the data and the inclusion of crops and formulation type, and further separate analysis and discussion would be required. However, it is a valuable exercise to estimate the level of conservatism of the current EFSA approach.

5. Conclusions

Bayesian analysis of the complete database suggested that the most important variables influencing drift were drift reduction, boom height, wind speed, mannequin height, distance downwind, crop class and formulation class. All of these except crop class and formulation class are included in BREAM 2. In addition, there was an interaction between wind speed and drift reduction, with DR nozzles being less affected by wind speed. This is not captured in BREAM 2 (although is predicted by the underlying drift model) because of the simplistic way drift reduction is included. However, it is likely that this is a relatively small effect and the approach taken in BREAM 2 remains conservative.

A comparison between BREAM 2 predictions and field measurements of potential bystander exposure have shown that the level of conservatism in the model is satisfactory and is therefore the most appropriate model currently available for risk assessment for bystanders and residents.

Comparing spray drift values, expressed as median, 75th and 95th percentiles, from the CLE data show that current EFSA guidance values significantly overestimate bystander/resident exposure.

CRediT authorship contribution statement

Edgars Felkers: Writing – review & editing, Writing – original draft, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Clare Butler Ellis:** Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Investigation, Formal analysis, Data curation. **Marc Kennedy:** Writing – review & editing, Writing – original draft, Validation, Software, Methodology, Investigation, Formal analysis. **Siân Wright-Williams:** Writing – review & editing, Data curation, Conceptualization. **Sarah Adham:** Writing – review & editing, Data curation, Conceptualization.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Edgars Felkers, Siân Wright-Williams, Sarah Adham are employees of companies that conduct and evaluate risk assessments for regulatory purposes in the context of authorization and marketing of their companies' products. They contribute as scientific experts to the industry association CropLife Europe for evaluation and development of the state-of-the-art methodology. Clare Butler Ellis and Marc Kennedy are employed by independent businesses which receive contract income from companies that conduct and evaluate risk assessments for regulatory purposes in the context of authorization and marketing of their companies’ products.

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Appendix A. Supplementary data

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Data availability

Data will be made available on request.

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