BYSTANDER AND RESIDENT EXPOSURE GUIDANCE

A bystander/resident exposure model is being developed. The Bystander and Residential Exposure Assessment Model (BREAM) is a DEFRA funded project which sets out to develop an exposure model to assess the potential exposure to pesticides for bystanders and residents. The BREAM project is due to be completed in 2010. The approaches outlined in this guidance document will be reviewed as the BREAM project progresses.

This document describes how CRD have recently assessed bystander/resident exposure for pesticides which are of low volatility and which are typically applied as sprays either by field crop (boom) sprayers broadcast air assisted (orchard) sprayers or hand held (knapsack) sprayers.

For pesticides applied as gases and those which act through significant vapour action, for example fumigants and soil sterilants, compound specific data on residues in air during and following application are required to support approval. Applicants are invited to discuss any proposals for conducting such work with CRD prior to generating these data.

Introduction

Bystanders are not legally defined either in national regulations (Control of Pesticides Regulations 1986) or under Directive 91/414/EEC. For the approval of pesticides in the UK bystanders, who include residents, are defined as follows:

**Bystanders are:** persons who are located within or directly adjacent to the area where pesticide application or treatment is in process or has been made; whose presence is quite incidental and unrelated to work involving pesticides but whose position may put them at risk of potential exposure; who take no action to avoid or control exposure and for whom it is assumed that no protective clothing is worn and perhaps little ordinary clothing.

**Residents are:** persons who live, work or attend school or any another institution adjacent to an area that has been treated with a plant protection product; whose presence is quite incidental and unrelated to work involving pesticides but whose position may put them at risk of potential exposure; who take no action to avoid or control exposure; for whom it is assumed that no protective clothing is worn and perhaps little ordinary clothing and who might be in the location for 24 hours per day.

Exposure Assessment

For assessing the exposure of bystanders and residents the exposure assessment submitted to support approval must consider each of following three scenarios;

1. **Exposure from spray drift at the time of application**

An estimate of the levels of spray drift deposited on the body of a bystander/resident and that which may be in the breathing zone and should be made. From this the amount of active substance available for dermal absorption and which may be inhaled
can be estimated. It should be assumed that no action is taken to avoid or control exposure and that little clothing is worn.

Measurements of bystander exposure during UK field crop spraying and orchard spraying applications have been reported by Lloyd and Bell, 1983 and Lloyd et al, 1987. For boom sprayers the average potential dermal exposure (PDE) for a bystander, positioned 8 metres downwind from the sprayer and the average amount of spray passing through the breathing zone were 0.1 ml spray/person and 0.006 ml spray/person, respectively. For orchard sprayer applications the equivalent PDE and inhalation values were 3.7 ml spray/person and 0.002 ml spray/person.

An approach using the orchard sprayer and boom sprayer data to predict bystander exposure is reported in the draft assessment report (DAR) for triadimenol and is included at Appendix 1. Levels of spray drift from applications made using hand held sprayers would not be expected to exceed those from boom sprayer applications. An exposure assessment using the boom sprayer PDE and inhalation values may therefore be used in the absence of spray drift data for hand-held applications.

2. Exposure from inhalation of pesticide which volatilises from the crop or soil surface after the application has been made

This part of the exposure assessment concerns the potential for longer term exposure to pesticide vapour which may occur after the plant protection product has been applied, for example residents who live adjacent to an area that has been treated with a plant protection product and who might be in this location for 24 hours per day.

A large number of non UK studies have been published which report the monitoring of outdoor air concentrations of pesticides after they have been applied to crops. From these studies the highest 24 hour time weighted average concentration in air for orchard sprayers (and a 21 hour time weighted average value for boom sprayer applications) have been determined. These values may be used generically. The draft assessment report (DAR) for triadimenol provides an example of how these air concentrations of pesticide may be used generically to predict the exposure for a resident. This example is included at Appendix 1.

Note that the current UK approach, after consideration by the UK Advisory Committee on Pesticides (ACP) in response to public concerns regarding bystander/resident exposure, is to use the more precautionary 24 hour time weighted average value for orchard sprayers in first tier assessments for all scenarios, including applications made by boom sprayer. The 21 hour time weighted average value for boom sprayers may be used as a refinement when necessary. The triadimenol example for boom sprayers should, therefore, only be followed in this situation.

3. Exposure through contact with contaminated surfaces following re-entry.

It is possible that spray drift fallout from applications may be deposited in private gardens adjacent to treated areas, and individuals in such locations may become exposed through contact with such deposits. A possible scenario that illustrates a significant opportunity for exposure would be children playing in a garden which has been subject to spray drift fallout. It is possible to estimate such exposures using spray
drift fallout values used for aquatic risk assessment purposes (Rautmann et al, 2001) and the approach used by the United States Environmental Protection Agency to estimate residential exposure from contact with treated lawns (USA EPA 1998 / 1999 / 2001). The exposure assessment reported in the DAR for triadimenol considers the scenario of a small child playing on a lawn. Assessments are given for applications made to vines using broadcast air assisted sprayers and to low crops using boom sprayers and these examples are included at Appendix 1. For applications made to high crops such as tree fruit using broadcast air assisted sprayers levels of drift would be expected to be higher than those made to vines (Rautmann et al, 2001) and an average drift value of 10% should be used instead of the 5.4% which is used for applications to vines.

For products which may be applied to crops on more than one occasion the theoretical worse case is to consider children’s exposure from the maximum total dose which may be applied, i.e. to assume that there is no dissipation in foliar residues between successive treatments. This approach may be refined where data are available to refine the estimated residues.

Summary

The approaches discussed above, which are reported in the triadimenol DAR, have been used by CRD to address the potential for bystanders to be exposed at the time of application (i.e. spray drift), once the application has been made (spray vapour) and through re-entry into areas where spray drift fallout has occurred (children’s exposure through play). Applicants may provide their own assessments based on alternative approaches and/or datasets provided these produce an appropriate exposure assessment for each of these exposure scenarios.

References


Appendix 1

EXTRACT FROM DRAFT ASSESSMENT REPORT FOR TRIADIMENOL

B.6.14.2 Bystander exposure (IIIA 7.2.2)

Broadcast Air Assisted and Knapsack sprayers - Vines

An estimate of bystander exposure during applications to vines is presented by this evaluation, based on a study conducted by Lloyd et al. (1987), which reports direct measurements of simulated bystander exposure for broadcast air assisted applications made to orchards in the UK. The average potential dermal exposure for a bystander, positioned 8 metres downwind from the sprayer and the average amount of spray passing through the breathing zone were 3.7 and 0.002 ml spray/person, respectively.

Using these data total systemic exposure can be estimated as follows:

\[
\text{Systemic exposure} = \frac{(\text{PDE} \times \text{SC} \times \% \text{ absorbed} + \text{PIE} \times \text{SC} \times 100\%) / \text{BW}}
\]

Where:
- PDE = potential dermal exposure (ml spray)
- PIE = potential inhalation exposure (ml spray)
- SC = concentration of active substance in spray
- % absorbed = percentage dermal absorption (i.e. 17%)
- BW = bodyweight (60 kg)

\[
\text{ml spray dermal} \times \frac{\text{mg/ml}}{1000} \times \frac{\% \text{ absorbed}}{100} + \text{ml inhaled mg/ml} \times \frac{0.313}{1000} = \frac{0.0033 \text{ mg/kg bw/day}}{60 \text{ kg bw}}
\]

Assuming an application of 62.5 g triadimenol in 200 litres water, no protection from clothing and 100% inhalation, retention and absorption of PIE, the estimated bystander exposure is 0.0033 mg/kg bw. This is equivalent to 33% of the AOEL of 0.01 mg/kg bw/day.

This estimate of exposure for applications from broadcast air assisted sprayers is expected to represent a worse case for equivalent applications of ‘Bayfidan EC 250’ to vines made using knapsack sprayers.

Indicative exposures for adults and children to triadimenol vapour post application following applications of ‘Bayfidan EC 250’ made via broadcast air assisted sprayers is predicted using a surrogate value for residues in air adjacent to treated crops from Califormian Environmental Protection Agency studies. Monitoring of chlorpyrifos residues in air over 72 hours adjacent to a 24 ha orange orchard provided a highest time weighted average estimate of 15 µg/m³/24h during application using air assisted sprayers. Time weighted average estimates for each of the 24 hour periods monitored were of 13, 15 and 4.9 µg/m³/24h. The meteorological conditions recorded during the chlorpyrifos study included wind speeds up to 20 km/h during application (the application was stopped on the first day of application due to rising wind speeds) and temperatures up to 42°C. These data are expected to represent
a worse case for triadimenol as chlorpyrifos (vapour pressure $2.3 \times 10^{-3}$ Pa at 25 °C) is a significantly more volatile compound than triadimenol which has a low vapour pressure ($1 \times 10^{-6}$ Pa at 25 °C (Diastereomer A) or $9 \times 10^{-7}$ Pa at 25 °C (Diastereomer B)).

An adult weighing 60 kg and a 3-5 year old child weighing 15 kg$^1$, breathing 15.2 and 8.3 m$^3$/day$^2$, respectively, of air containing 15 µg/m$^3$/24h would potentially be exposed to 0.0038 and 0.0083 mg/kg bw/d. Whilst the children’s indicative exposure is below the AOEL (83%), in view of the differences in volatility between chlorpyrifos and triadimenol this exposure model is expected to over estimate air residues of triadimenol post application. It is also noted that the 15 µg/m$^3$/24h TWA value was the highest of the three concurrent 24 hour periods monitored and repeated exposure would not be expected at these air levels.

It is also possible spray drift fallout from applications may be deposited in gardens adjacent to treated areas, and individuals in such locations may become exposed through contact with such deposits. It is possible to estimate such exposures using the spray drift fallout values used for the aquatic risk assessment and the approach used by the United States Environmental Protection Agency to estimate residential exposure from contact with treated lawns. The following exposure assessment considers the scenario of a small child playing on a lawn.

1) Spray drift fallout

Allowing for a headland of 3m within the vineyard, for machinery to operate within, at the boundary of a neighbouring area the level of fallout (from late season applications when leaves are present) could be equivalent to 8.02% of the field rate. The level of deposit would decline away from the boundary to just over 3.6% at 5 metres$^3$. An estimate, by integration, of the average level of fallout over the whole area from the boundary to 5 metres would be about 5.4%.

2) Children’s dermal exposure

Systemic exposures via the dermal route were calculated using the above drift fallout values and the following equation:

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$^1$ Adults 60 kg is the 50th percentile for UK 16-24 yrs females, children 15 kg is the average values for UK 2 and 3 yrs males and females: 1995-7 Health Surveys for England.

$^2$ Long term inhalation rates (mean values) for adult males (19-65 + yrs) for children 3-5 yrs: US EPA Exposure Factors Hand Book

### Systemic Exposure via the Dermal Route

<table>
<thead>
<tr>
<th>AR</th>
<th>DF</th>
<th>TTR</th>
<th>TC</th>
<th>H</th>
<th>DA</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE(d) = 3.75 x 5.4% x 5% x 5200 x 2 x 17%</td>
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<td>BW</td>
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<tr>
<td>1.19 µg/kg bw</td>
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</table>

Where:
- **SE(d)** = systemic exposure via the dermal route
- **AR** = field application rate, 0.0625 kg/ha x 6 applications = 3.75 µg/cm²
- **DF** = drift fallout value, i.e. assumed average of 5.4% from broadcast air assisted sprayer applications
- **TTR** = turf transferable residues – the EPA default value of 5% was used in the estimate
- **TC** = transfer coefficient – the standard EPA value of 5200 cm²/h was used for the estimate
- **H** = exposure duration for a typical day (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook
- **DA** = percent dermal absorption
- **BW** = body weight - 15 kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs.

### Children’s Hand-to-Mouth Exposure

Hand-to-mouth exposures were calculated using turf transferable residue levels using the following equation:

<table>
<thead>
<tr>
<th>AR</th>
<th>DF</th>
<th>TTR</th>
<th>SE</th>
<th>SA</th>
<th>Freq</th>
<th>H</th>
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</thead>
<tbody>
<tr>
<td>SE(h) = 3.75 x 5.4% x 5% x 50% x 20 x 20 x 2</td>
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<td>15</td>
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<tr>
<td>BW</td>
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<tr>
<td>0.27 µg/kg bw</td>
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</tbody>
</table>

Where:
- **SE(h)** = systemic exposure via the hand-to-mouth route
- **AR** = field application rate, 0.0625 kg/ha x 6 applications = 3.75 µg/cm²
- **DF** = drift fallout value, i.e. assumed average of 5.4% from broadcast air assisted sprayer applications
- **TTR** = turf transferable residues – the EPA default value of 5% derived from transferability studies with wet hands was used in the estimate
- **SE** = saliva extraction factor – the default value of 50% was used
- **SA** = surface area of the hands – the assumption used here is that 20 cm² of skin area is contacted each time a child puts a hand in his or her mouth (this is equivalent to the palmer surface of three figures and is also related to the next parameter)
- **Freq** = frequency of hand to mouth events/hour – for short term exposures the value of 20 events/hours is used, this is the 90th percentile of observations that ranges from 0 to 70 events/hour
- **H** = exposure duration (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook
- **BW** = body weight - 15 kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs.
4) Children’s object-to-mouth exposure

Object to mouth exposures were calculated using turf transferable residue levels using the following equation

\[
SE(o) = \frac{AR \times DF \times TTR \times IgR}{BW}
\]

Where:
- \( SE(o) \) = systemic exposure via mouthing activity
- \( AR \) = field application rate, 0.0625 kg/ha x 6 applications = 3.75 µg/cm²
- \( DF \) = drift fallout value, i.e. assumed average of 5.4% from broadcast air assisted sprayer applications
- \( TTR \) = turf transferable residues the default value of 20% transferability from object to mouth assessments was used
- \( IgR \) = ingestion rate for mouthing grass/day – this was assumed to be equivalent to 25cm² of grass/day
- \( BW \) = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs.

\[
\begin{array}{c|c|c|c|c|c}
& AR & DF & TTR & IgR \\
SE(o) = & 3.75 & x & 5.4\% & 20\% & x & 25 & \\
15 & & & & & & \\
BW & & & & & & 0.068 \mu g/kg bw
\end{array}
\]

5) Children’s total exposure

Children’s total exposure was estimated as the sum of the dermal, hand-to-mouth, and object to mouth exposures, which was 0.00153 mg/kg bw/day (1.53 µg/kg bw/d).

**Broadcast Air Assisted and Knapsack sprayers – Orchard application**

Application to tree fruit such as pome fruit using broadcast air assisted sprayers was not considered for the supported uses of triadimenol. The same methodology used for estimating exposure to vines would be used for estimating exposure from tree fruit applications, with the exception of spray drift fallout.

Allowing for a realistic headland of 5m within the orchard, for machinery to operate within, at the boundary of a neighbouring area the level of fallout (from early season applications when leaves are not present) could be equivalent to about 20% of the field rate. The level of deposit would decline away from the orchard boundary to just over 5% at 10 metres⁴. An estimate of the average level of fallout over the whole area from the boundary to 10 metres would be about 10%. This would give a deposit of about 1 µg/cm²/kg applied/ha. Later season fall out levels, would be lower as a result of the crop canopy.

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Field crop (boom) sprayers – cereals

An estimate of bystander exposure has been made by this evaluation, based on a published UK study (Lloyd and Bell, 1983) in which measurements of simulated bystander exposure were made during field crop spraying operations. The average potential dermal exposure for a bystander, positioned 8 metres downwind from the sprayer and the average estimated amount of spray passing through the breathing zone were 0.1 and 0.006 ml spray/person, respectively.

Using these data total systemic exposure can be estimated as follows:

\[
\text{Systemic exposure} = \frac{(\text{PDE} \times \text{SC} \times \% \text{ absorbed} + \text{PIE} \times \text{SC} \times 100\%) \times \text{BW}}{	ext{BW}}
\]

Where:
- \( \text{PDE} \) = potential dermal exposure (ml spray)
- \( \text{PIE} \) = potential inhalation exposure (ml spray)
- \( \text{SC} \) = concentration of active substance in spray
- \( \% \text{ absorbed} \) = percentage dermal absorption (i.e. 17%)
- \( \text{BW} \) = bodyweight (60 kg)

\[
\begin{align*}
\text{ml spray dermal} &\quad \text{mg/ml} &\quad \% \text{ absorbed} &\quad \text{ml inhaled mg/ml} \\
0.1 &\quad 0.625 &\quad 17 &\quad 0.01 \times 0.63
\end{align*}
\]

\[
\begin{align*}
= 0.0002 &\quad \text{mg/kg bw/day} \\
60 &\quad \text{kg bw}
\end{align*}
\]

Assuming an application of 125 g triadimenol in 200 litres water, no protection from clothing and 100% inhalation, retention and absorption of PIE, the estimated bystander exposure is 0.00024 mg/kg bw. This is equivalent to <3% of the AOEL.

For applications made using field crop (boom) sprayers, exposure to vapour post application is predicted from studies conducted in Germany, where lindane (vapour pressure = 5.6 x 10^{-3} Pa at 25 °C), parathion (1.3 x 10^{-3} Pa at 25 °C) and pirimicarb (4 x 10^{-3} Pa at 25 °C) were applied in field trials to provide measurements of residues in air adjacent to treated crops (Siebers et al 2000). Each active substance was applied at the same rate (g a.s./ha) and in the same water volume. Applications were achieved using field crop sprayers fitted with 12 metre booms. Monitoring of residues in air over 21 hours, 10 metres downwind of treated barley plots, provided 21 hour time weighted air concentrations of 0.29 and 0.58 µg/m^3 (lindane), 0.07 and 0.12 µg/m^3 (parathion) and <0.02 and 0.04µg/m^3 (pirimicarb). The meteorological conditions during the trial included wind speeds of up to 23.4 km/h and temperatures up to 28°C. The study authors report wind speeds in the second trial (Trial B) were significantly higher (2 to 3X) than in the first trial (Trial A) and this is expected to have contributed to the variability of these results. It is noted that the higher 21 hour TWA value for each active substance was determined from Trial B.

In view of the small size of this data set (2 trials for each of the three active substances) a precautionary approach is to use a value of 1 µg/m^3 to predict bystander exposure from vapour after application of the spray. An adult
weighing 60 kg and a 3-5 year old child weighing 15 kg, breathing 15.2 and 8.3 m³/day, respectively, of air containing this residue level, would potentially be exposed to 0.000253 and 0.0006 mg/kg bw/d. The highest of these is 6% of the AOEL.

It is also possible spray drift fallout from applications may be deposited in gardens adjacent to treated areas, and individuals in such locations may become exposed through contact with such deposits. It is possible to estimate such exposures using the spray drift fallout values used for the aquatic risk assessment, and the approach used by the United States Environmental Protection Agency to estimate residential exposure from contact with treated lawns. The following exposure assessment considers the scenario of a small child playing on a lawn where the indicative exposure is 0.0002 mg/kg bw/d.

1) Spray drift fallout

Allowing for an untreated headland of 1 m, the level of fallout from spray drift at the boundary with a neighbouring area is predicted to be equivalent to 2.77% of the applied dose. This level of fallout deposit is predicted to decline to 0.57% at a distance of 5 m from the boundary. By integration, the average level of fallout over the whole area from the boundary to a point 3 m outside is estimated to be about 1%.

2) Children’s dermal exposure

Systemic exposures via the dermal route were calculated using the above drift fallout values and the following equation:

\[
SE(d) = \frac{AR \times DF \times TTR \times TC \times H \times DA}{BW}
\]

Where:
- \(SE(d)\) = systemic exposure via the dermal route
- \(AR\) = field application rate, 0.125 kg/ha x 2 applications = 2.5 µg/cm²
- \(DF\) = drift fallout value, i.e. assumed average of 1% from field crop (boom) sprayer applications
- \(TTR\) = turf transferable residues – the EPA default value of 5% was used in the estimate
- \(TC\) = transfer coefficient – the standard EPA value of 5200 cm²/h was used for the estimate
- \(H\) = exposure duration for a typical day (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook
- \(DA\) = percent dermal absorption
- \(BW\) = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs.
3) Children’s hand-to-mouth exposure

Hand-to-mouth exposures were calculated using turf transferable residue levels using the following equation:

\[
SE(h) = \frac{AR \times DF \times TTR \times SE \times SA \times Freq \times H}{BW}\]

Where:
- \( SE(h) \) = systemic exposure via the hand-to-mouth route
- \( AR \) = field application rate, 0.125 kg/ha x 2 applications = 2.5 µg/cm\(^2\)
- \( DF \) = drift fallout value, i.e. assumed average of 1% from field crop (boom) sprayer applications
- \( TTR \) = turf transferable residues – the EPA default value of 5% derived from transferability studies with wet hands was used in the estimate
- \( SE \) = saliva extraction factor – the default value of 50% was used
- \( SA \) = surface area of the hands – the assumption used here is that 20 cm\(^2\) of skin area is contacted each time a child puts a hand in his or her mouth (this is equivalent to the palmer surface of three figures and is also related to the next parameter)
- \( Freq \) = frequency of hand to mouth events/hour – for short term exposures the value of 20 events/hours is used, this is the 90th percentile of observations that ranges from 0 to 70 events/hour
- \( H \) = exposure duration (hours) – this has been assumed to be 2 hours which matches the 75th percentile for toddlers playing on grass in the EPA Exposure Factors Handbook
- \( BW \) = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs.

\[
SE(h) = \frac{2.5 \times 1\% \times 5\% \times 50\% \times 20 \times 20 \times 2}{15BW} = 0.033 \text{ µg/kg bw}
\]
4) **Children’s object-to-mouth exposure**

Object to mouth exposures were calculated using turf transferable residue levels using the following equation

\[
SE(o) = \frac{AR \times DF \times TTR \times IgR}{BW}
\]

\[
= \frac{2.5 \times 1\% \times 20\% \times 25}{15BW}
\]

\[
= 0.008 \, \mu g/kg \, bw
\]

Where:
- **SE(o)** = systemic exposure via mouthing activity
- **AR** = field application rate, 0.125 kg/ha x 2 applications = 2.5 µg/cm²
- **DF** = drift fallout value, i.e. assumed average of 1% from field crop (boom) sprayer applications
- **TTR** = turf transferable residues the default value of 20% transferability from object to mouth assessments was used
- **IgR** = ingestion rate for mouthing grass/day – this was assumed to be equivalent to 25cm² of grass/day
- **BW** = body weight - 15kg which is the average of UK 1995-7 Health Surveys for England values for males and females of 2 and 3 yrs.

5) **Children’s total exposure**

Children’s total exposure was estimated as the sum of the dermal, hand-to-mouth, and object to mouth exposures, which was 0.0002 mg/kg bw/day (0.19 µg/kg bw/d).