Bystander & Resident Exposure to Plant Protection Products
Available Data and the EFSA Guidance

Alan MacDonald
Exposure Branch
Chemicals Regulation Directorate, UK
Bystanders

- Located in or directly adjacent to area being treated or recently treated with PPP
- Presence incidental
- Not work related to PPP use
- Take no action to avoid or control exposure
- May be lightly clothed
- Likely to have short-term / acute exposure
Residents

- Live, work, at school, etc. adjacent to area being treated (has been treated) with PPP
- Presence incidental
- Not work related to PPP use
- Take no action to avoid or control exposure
- May be lightly clothed
- Might be in location all day leading longer-term exposure
EFSA Guidance – resident & bystander risk assessment

• Four step approach
• Step 1: identification of risk assessments that are required
  – Is PPP acutely toxic?
  – AOEL, AAOEL

<table>
<thead>
<tr>
<th>Exposed group</th>
<th>PPP - no acute systemic toxicity</th>
<th>PPP - potential for acute systemic toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resident</td>
<td>Longer term</td>
<td>Longer term (acute exposure covered by bystander)</td>
</tr>
<tr>
<td>Bystander</td>
<td>Longer term (covered by resident)</td>
<td>Acute</td>
</tr>
</tbody>
</table>
EFSA Guidance – resident & bystander risk assessment

• Step 2: use standardised first tier methods.
• Step 3: use appropriate *ad hoc* methods where standard first tier methods are not available.
• Step 4: higher tier exposure assessment.
• In practice, limited options to refine first tier resident / bystander assessment.
Four pathways of bystander and resident exposure

• Spray drift (during application)
  — Short term event
  — Dermal and inhalation

• Vapour (occurring after PPP applied)
  — Inhalation

• Surface deposits (drift fallout) in adjacent areas
  — Direct dermal, hand to mouth, object to mouth

• Entry into treated crops
  — Dermal contact with foliage
Resident (longer term) risk assessment

- Exposure from each pathway based upon 75\textsuperscript{th} percentile values
- Also calculate mean exposure values & sum exposure pathways
- Compare to AOEL
Bystander (acute) risk assessment

• Exposure from each pathway based upon 95th percentile values
• No summing of exposure pathways
  – Unrealistic
• Compare to AAOEL
Vapour exposure available data

- Siebers et al 2003 Chemosphere 51 397-407
- Expect more from BROWSE project
Vapour exposure EFSA Guidance

- Vapour (24 hour exposure period)
- Moderate volatility
  - \( VP \geq 0.005 \text{ Pa and } < 0.01 \text{ Pa} \)
  - California EPA
    - 15 \( \mu g/m^3 \)
- Low volatility
  - \( VP < 0.005 \text{ Pa} \)
  - Siebers et al
    - 1 \( \mu g/m^3 \)
## Volatility: recent UK data for cereal fungicides

<table>
<thead>
<tr>
<th>Active</th>
<th>Vapour pressure (EFSA)</th>
<th>Air concentration of vapour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tebuconazole</td>
<td>$1.3 \times 10^{-6}$ Pa at 20 °C</td>
<td>0.003 µg/m³</td>
</tr>
<tr>
<td>Prothioconazole</td>
<td>$&lt;4 \times 10^{-7}$ Pa at 20 °C</td>
<td>0.059 µg/m³</td>
</tr>
<tr>
<td>Epoxiconazole</td>
<td>$1.0 \times 10^{-5}$ Pa at 20 °C</td>
<td>0.066 µg/m³</td>
</tr>
<tr>
<td>Fenpropidin</td>
<td>$1.7 \times 10^{-2}$ Pa at 25 °C</td>
<td>7.3 µg/m³</td>
</tr>
</tbody>
</table>
Spray drift available data

- UK Government lab arable study Lloyd & Bell 1983, orchard study Lloyd et al 1987
- EU SMT project SMT4-CT96-2048
- DE BBA/JKI Basic Drift Values
- UK BREAM project 2010
- Expect more from BROWSE project and industry data
Current UK Approach
Boom and Orchard Sprayers
Lloyd et al simulated bystander exposure data

- Field crop sprayer single pass
- Orchard sprayer (whole orchard)
- Mean PDE and mean PIE
BREAM Project

• Generate new data
  – Boom sprayers only
  – Modern equipment
  – Closer distances
  – Adults and children

Picture courtesy of Silsoe Spray Applications Unit, The Arable Group
BREAM drift trials video clip
XR 03 nozzle, 0.7 m, 16 km/h
Spray drift EFSA guidance

• Field crop (boom) sprayer data derived from BREAM (2010) at 2m, 5m and 10m from field edge. Adult and child data.

• Broadcast air-assisted (orchard) sprayer data derived from Lloyd et al (1987) at 5m (only) from orchard edge. Adult data only – scaled for child.

• Values for hand-held application from boom and orchard sprayer data

• Adjustment for light clothing
# Spray drift EFSA Guidance

<table>
<thead>
<tr>
<th>Method of application</th>
<th>Dermal exposure</th>
<th>Inhalation exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adults</td>
<td>Children</td>
</tr>
<tr>
<td>Boom applications (2 m)</td>
<td>0.47 ml (R)</td>
<td>0.33 ml (R)</td>
</tr>
<tr>
<td></td>
<td>1.21 (B)</td>
<td>0.74 ml (B)</td>
</tr>
<tr>
<td></td>
<td>(UK 0.1 ml)</td>
<td></td>
</tr>
<tr>
<td>Broadcast air assisted applications (5 m from edge)</td>
<td>5.63 ml (R)</td>
<td>1.689 ml (R)</td>
</tr>
<tr>
<td></td>
<td>12.9 ml (B)</td>
<td>3.87 ml (B)</td>
</tr>
<tr>
<td></td>
<td>(UK 3.7 ml)</td>
<td></td>
</tr>
</tbody>
</table>
Surface deposits EFSA Guidance

• Drift values from BREAM and Rautmann/Ganzelmeier
  – Longer term 75\textsuperscript{th} percentile and mean
  – Acute 95\textsuperscript{th} percentile
• 2 h exposure period
• Adult
  – Direct dermal route only
• Child
  – Direct dermal, Hand to mouth, Object to mouth
• TC values for adults and children
  – Longer term (75\textsuperscript{th} percentile)
  – Acute (95\textsuperscript{th} percentile)
Entry into treated crops EFSA Guidance

• Same assessment for residents and bystanders
• DFR x TC x T
• 15 minute exposure period
• TC values (adult crop inspection task)
• Adult to child factor
Human aspects

• Body weight

• Breathing rate (based on US EPA)
  – Adult and child
  – Short-term exposure high hourly rate
  – Longer-term exposure daily average rate

• Light clothing over trunk (spray drift only)
Future developments: acute risk assessment for bystanders

- Adoption of guidance / model ahead of AAOEL setting
- Plan to draft guidance on AAOEL setting discussed at EC SC
- ARfD taking into account incomplete oral absorption
Future developments: use of BROWSE data?

• Vapour exposure
  – Better than limited (single values) from CA EPA and Siebers
  – Validated for use in mechanistic fate model (PEARL OPS)
  – Can take account of typical air flows, dilution etc.

• Field crop (boom) sprayer drift data
  – More options than BREAM (validated for short crop and 03 nozzle)
  – Improved predictive (‘what if’) modelling for airborne drift and bystander contamination

• Broadcast air-assisted (orchard) sprayer drift data
  – Empirical model only (UK and NL studies) – less scope for ‘what if’ predictions
Higher tier approaches for bystanders and residents

• CRD informal consideration of EFSA approach
  – 50 most used actives (50 representative products)
  – Approximately 2% failed on bystander exposure based on assumed AAOEL

• Vapour exposure > AOEL or AAOEL
  – BROWSE as higher tier?

• Drift, fallout, re-entry exposure > AOEL or AAOEL
  – Buffer zones?
  – Low drift nozzles?

• Possible refinements as agreed/peer-reviewed additions to database?
Thank you for your attention