Laubwandfläche (Leaf Wall Area) als Bezugsfläche für die Pflanzenschutzmitteldosierung in Raumkulturen - Einfluss auf die Dosis-Wirkungsbeziehung in Feldversuchen sowie die Europäische Pflanzenschutzmittelzulassung

Dose Rate Expression in Tree Fruits – The Need for a Harmonized Approach from an Industry Perspective

An Industry Proposal of BASF, Bayer CS, Dow AS, DuPont AS, Makhteshim Agan and Syngenta

Content

- Background
- Current dose expressions units
- Why Leaf Wall Area (LWA)
- How to convert between the different dose expression units
- Data capturing in efficacy trials
- Benefits of LWA
- Current status
- Q&A
In the discussion we should keep in mind that...

• We must distinguish between…
  
  • Dose expression = the unit in which the dose is expressed and the
  • Dose rate = the quantity of product necessary to achieve the required
    efficacy = result of dose finding work
  • Dose rate adjustment

This presentation deals with the proposal to use one common dose expression unit for efficacy trials

• In view of the new zonal registration system in the EU, a dose harmonisation is first of all a help for regulators (efficacy and risk assessment).

• The dose expression harmonisation approach is by no means a tool to increase dose rates, but
  can be the platform for dose adjustments.
Background

• The topic is not new at all. It has been discussed amongst specialists for approx. 20 years, but no agreement was achieved

• The **ECPA Efficacy Expert Group (EffEG)** discussed the topic dose expression on January 24, 2011. Extract from the minutes:
  • *This is potentially an issue for the zonal process if there is no agreement between Member States regarding how to express dose rates in high crops.*
  • *It was agreed that an industry sub-group is set up with members of EffEG and application specialists from interested companies to agree a methodology. Syngenta agreed to lead this initiative and host a potential meeting.*

The primary objectives of the industry sub-group are:
• To obtain an industry wide agreement regarding dose expression (LWA)
• To present the agreement to the full EPPO group on October 19, 2011 in Brussels

• In addition, the topic was discussed at the **EPPO Standards Panel** meeting in March 2011 in Braunschweig, Germany.
## Current dose rate expression units used in Europe

<table>
<thead>
<tr>
<th>Country</th>
<th>Top fruits</th>
<th>Grapevine</th>
<th>High-growing vegetables</th>
<th>Citrus / Olives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria and Germany</td>
<td>Kg/ha/m CH, max. kg/ha % accord. Eichhorn, max. kg/ha BBCH</td>
<td>Kg/ha/m CH, max. kg/ha</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Belgium</td>
<td>Kg or L/10'000m² LWA, max. kg or l/ha</td>
<td>---</td>
<td>Kg/ha</td>
<td>---</td>
</tr>
<tr>
<td>France</td>
<td>Kg/ha</td>
<td>Kg/ha</td>
<td>Kg/ha</td>
<td>---</td>
</tr>
<tr>
<td>Netherlands</td>
<td>%, max. spray vol / ha</td>
<td>---</td>
<td>%, max. spray vol / ha</td>
<td>---</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Kg/10'000 m³ TRV</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
<td>---</td>
</tr>
<tr>
<td>Norway</td>
<td>Kg/100m row length</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Greece</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
</tr>
<tr>
<td>Italy</td>
<td>%, min. to max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
</tr>
<tr>
<td>Portugal</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
</tr>
<tr>
<td>Spain</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
<td>%, max. spray vol / ha</td>
</tr>
</tbody>
</table>

**6 different dose expression units for top fruits!**

**CH:** Canopy Height  
**LWA:** Leaf Wall Area  
**TRV:** Tree Row Volume
To link the dose rate with the spray volume (% concentration or ml or gr/hl) can lead to very different dose rates / ha. Data comparison difficult.
Why a new unit: Efficacy results on ground area basis

Accurate dose setting is difficult!
Pharmaceuticals: dose rate adapted to the body weight

- 15 kg child
- 55 kg lady - teacher
- 100 kg worker

Logical - Accepted by all
Agriculture: dose rate adapted to the size of the crop

Principle: foliar applications should result in similar deposits per e.g. cm²
Industry proposal – Leaf Wall Area (LWA)

LWA = 2 x (canopy height / row distance) x ground area
Why a new unit: Efficacy results on leaf wall area basis

Accurate dose setting is much easier!
Conversion of the different dose models for high crops

- Concentration (%)
- Dose (kg/ha)
- Spray volume L/ha
- Canopy height m
- Row distance m
- Leaf wall area (kg per 10'000 m² LWA)
- Leaf wall height (kg/ha and m CH)

Parameters needed to convert the different dose models

• row distance (m)
• canopy height (m)
• applied water volume (l/ha)
• dose (kg or L/ha)

• tree or foliage width (m) for conversion to TRV

We can cope with regulatory requirements of all countries
**Conversion of different dose models**

<table>
<thead>
<tr>
<th>Conversion to rate per ha ground area</th>
<th>Conversion Formula</th>
<th>Example</th>
</tr>
</thead>
</table>
|                                       | \( rate_{GA} = \frac{x \cdot LWA}{10000} \) | • application rate \( x \): 0.8 l / 10'000 m² LWA  
• foliage height: 3.5 m  
• row distance: 4.0 m  
• LWA: 17'500 m² / ha ground area  
• spray volume: 1’500 l/ha ground area |
|                                       | \( rate_{HL} = \frac{x \cdot LWA}{SPV \cdot 100} \) | \( \approx \)  
rate_{HL} \( \approx 0.09 \) l/hl |
| Conversion to rate per ha ground area and per m foliage height | \( rate_{FH} = \frac{x \cdot 2}{row \ distance} \) | \( \approx \)  
rate_{FH} \( \approx 0.40 \) l/ha/m FH |

Source: Syngenta Crop Protection, 2011
Data Capture in ARM (Syngenta)

- In Site Description / Crop Stage

### Automatic Calculations

- Height Min, Max, Unit: 210.0, 280.0 CM
- Plant Diameter Min, Max, Unit: 115.0 CM
- Foliage Height, Unit: 1.3
- T/H Row Spacing, Unit: 2.4 M
- Tree/Crop Row Volume (m³/ha):
  - Row Spacing, Unit: 3.0 M
  - Spacing Within Row, Unit: 1.0 M

### Manual Entries

- Date: 05.9.2011
- Variety: Kelkfrankos
- Crop: VITVI
- Crop Code, BBCH Scale: 1
- Row Diameter, in [M] or [CM]:
- Max spray band, in [M] or [CM]:
- Min spray band, in [M] or [CM]:
- Planting Date: 15.6.1995
- Emergence Date: 
- Planting Type: TRA
- Planting Type Description: Transplanting
- Planting/Pruning System: 
- Ground Cover: 
- Planting Depth Min, Max, Unit: 
- Rootstock: 
- Seed Bed: 
- Genetic Type A: 
- Harvest Width, Unit: 
- Harvest Year, Unit: 

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Classification: INTERNAL USE ONLY
Data Capture in ARM (Syngenta)

**Protocol Instructions**

- *SPRAY VOLUME:*
  - if sprayed with backpack sprayer or gun the spray volume (+/- 10%) should be
    - LWA: 660
    - 10000: 600
    - 12000: 660
    - 14000: 720
    - 16000: 780
    - 18000: 840
  - if sprayed with (semi-)commercial equipment (air assisted areaal sprayer) the spray volume should be 300 - 600 l/ha

---

**Treatment List:**

<table>
<thead>
<tr>
<th>T</th>
<th>1</th>
<th>Products Syn.</th>
<th>Afs of Products</th>
<th>Product/AI Rates</th>
<th>Appl Typ</th>
<th>UA</th>
<th>Method</th>
<th>Placement</th>
<th>Timing</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>CHECK-UN</td>
<td></td>
<td></td>
<td>0,25 LPR/100000M2LWA</td>
<td>1</td>
<td>84</td>
<td>SPRAY</td>
<td>FOLIAR</td>
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<tr>
<td>2</td>
<td>1</td>
<td>A6580 (C,UN)</td>
<td>PENCONAZOLE</td>
<td>0,33 LPR/100000M2LWA</td>
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<td>84</td>
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<td>PRINFC</td>
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<tr>
<td>3</td>
<td>1</td>
<td>A16524 (AA,UN)</td>
<td>ISOBY -RAZAM</td>
<td>0,12 KGPR/10000M2WA</td>
<td>1</td>
<td>84</td>
<td>SPRAY</td>
<td>FOLIAR</td>
<td>PRINFC</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>A16099 (A,UN)</td>
<td>CYLFLUFENAMID</td>
<td>0,5 LPR/100000M2LWA</td>
<td>1</td>
<td>84</td>
<td>SPRAY</td>
<td>FOLIAR</td>
<td>PRINFC</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>FLINT 50 WG (UN)</td>
<td>TRIFLOXYSROBIN</td>
<td>TRIMATONOL (50)</td>
<td>0,13 KGPR/10000M2WA</td>
<td>1</td>
<td>84</td>
<td>SPRAY</td>
<td>FOLIAR</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>NIVROD (C,UN)</td>
<td>BIPREIMATE</td>
<td>0,5 LPR/100000M2LWA</td>
<td>1</td>
<td>84</td>
<td>SPRAY</td>
<td>FOLIAR</td>
<td>PRINFC</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>A19384 (A,UN)</td>
<td>PENTHOPYRAD (90)</td>
<td>0,85 LPR/100000M2LWA</td>
<td>1</td>
<td>84</td>
<td>SPRAY</td>
<td>FOLIAR</td>
<td>PRINFC</td>
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<tr>
<td>8</td>
<td>1</td>
<td>EXACT 50 EW (AA,UN)</td>
<td>TRIADINONOL (50)</td>
<td>0,13 KGPR/10000M2WA</td>
<td>1</td>
<td>84</td>
<td>SPRAY</td>
<td>FOLIAR</td>
<td>PRINFC</td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>STROBY 50 WG (UN)</td>
<td>KRESOXIM-METHYL (50)</td>
<td>0,13 KGPR/10000M2WA</td>
<td>1</td>
<td>84</td>
<td>SPRAY</td>
<td>FOLIAR</td>
<td>PRINFC</td>
</tr>
</tbody>
</table>
### Typical Leaf Wall Areas – the base of a future label

<table>
<thead>
<tr>
<th>Row distance (m)</th>
<th>1.5</th>
<th>2.0</th>
<th>2.5</th>
<th>3.0</th>
<th>3.5</th>
<th>4.0</th>
<th>4.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5</td>
<td>12'000</td>
<td>16'000</td>
<td>20'000</td>
<td>24'000</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>3.0</td>
<td>10'000</td>
<td>13'333</td>
<td>16'666</td>
<td>20'000</td>
<td>23'333</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>3.5</td>
<td>8'571</td>
<td>11'428</td>
<td>14'286</td>
<td>17'143</td>
<td>20'000</td>
<td>22'857</td>
<td>n.a.</td>
</tr>
<tr>
<td>4.0</td>
<td>7'500</td>
<td>10'000</td>
<td>12'500</td>
<td>15'000</td>
<td>17'500</td>
<td>20'000</td>
<td>22'500</td>
</tr>
<tr>
<td>4.5</td>
<td>6'666</td>
<td>8'888</td>
<td>11'111</td>
<td>13'333</td>
<td>15'555</td>
<td>17'777</td>
<td>20'000</td>
</tr>
<tr>
<td>5.0</td>
<td>6'000</td>
<td>8'000</td>
<td>10'000</td>
<td>12'000</td>
<td>14'000</td>
<td>16'000</td>
<td>18'000</td>
</tr>
</tbody>
</table>

= most common sizes for modern pome fruit orchards

Industry Data - LWA PER COUNTRY & ZONE

Filter Settings
- Max LWA: (5000.00 <= Max LWA <= 30000.00) and empty values

Color by EPPO Zone
- Central
- South

Reference points:
- Average
- Median

Max LWA

BELGIUM  GERMANY  NETHERL... UNITED K...  FRANCE  ITALY  PORTUGAL  SOUTH  SPAIN  SWITZERLAND

Count  88  343  103  11  348  527  142  502  265

Max LWA: (5000.00 <= Max LWA <= 30000.00) and empty values
Apple + pear: distribution of LWA in regulatory zones

The source data come from efficacy and residue trials in Europe from 2003-2011.

Key: line=median, diamond=mean, box=half data, whisker=box±1.5, points=outliers.
### Distribution of LWA by Fruit Trees groups (all countries together)

**Analysis Variable : LWA_calc Leaf wall area, calculated (m²/ha)**

<table>
<thead>
<tr>
<th>Crop name</th>
<th>N Obs</th>
<th>Mean</th>
<th>Lower 95% CL for Mean</th>
<th>Upper 95% CL for Mean</th>
<th>25th Pctl</th>
<th>50th Pctl</th>
<th>75th Pctl</th>
<th>90th Pctl</th>
<th>95th Pctl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple</td>
<td>900</td>
<td>13462</td>
<td>13226</td>
<td>13697</td>
<td>11000</td>
<td>13143</td>
<td>15000</td>
<td>18462</td>
<td>20000</td>
</tr>
<tr>
<td>Pear</td>
<td>321</td>
<td>13465</td>
<td>13023</td>
<td>13908</td>
<td>10476</td>
<td>13333</td>
<td>15333</td>
<td>18400</td>
<td>20000</td>
</tr>
<tr>
<td>Apricot</td>
<td>39</td>
<td>9200</td>
<td>8461</td>
<td>9939</td>
<td>7500</td>
<td>9020</td>
<td>11429</td>
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<tr>
<td>Nectarine</td>
<td>59</td>
<td>8770</td>
<td>7994</td>
<td>9546</td>
<td>7200</td>
<td>8000</td>
<td>10000</td>
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<tr>
<td>Peach</td>
<td>238</td>
<td>9565</td>
<td>9246</td>
<td>9885</td>
<td>8000</td>
<td>9798</td>
<td>10800</td>
<td>12500</td>
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<tr>
<td>Cherry</td>
<td>149</td>
<td>11353</td>
<td>10722</td>
<td>11984</td>
<td>8889</td>
<td>11628</td>
<td>13333</td>
<td>14222</td>
<td>17143</td>
</tr>
<tr>
<td>Plum</td>
<td>134</td>
<td>11614</td>
<td>11018</td>
<td>12209</td>
<td>10000</td>
<td>12000</td>
<td>14286</td>
<td>15556</td>
<td>17143</td>
</tr>
</tbody>
</table>

**Analysis Variable : LWA_calc Leaf wall area, calculated (m²/ha)**

<table>
<thead>
<tr>
<th>Crop group</th>
<th>N Obs</th>
<th>Mean</th>
<th>Lower 95% CL for Mean</th>
<th>Upper 95% CL for Mean</th>
<th>25th Pctl</th>
<th>50th Pctl</th>
<th>75th Pctl</th>
<th>90th Pctl</th>
<th>95th Pctl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pome</td>
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<td>13463</td>
<td>13254</td>
<td>13671</td>
<td>10667</td>
<td>13333</td>
<td>15152</td>
<td>18462</td>
<td><strong>20000</strong></td>
</tr>
<tr>
<td>Stone</td>
<td>619</td>
<td>10340</td>
<td>10079</td>
<td>10601</td>
<td>8000</td>
<td><strong>10000</strong></td>
<td>12500</td>
<td>15000</td>
<td>15556</td>
</tr>
</tbody>
</table>

Analysis by Peter Lancashire (SAS 9.2 on 14OCT2011 at 10:15) . . . © Bayer CropScience AG

The source data come from efficacy and residue trials in Europe from 2003-2011.

Key: line=median, diamond=mean, box=half data, whisker=box±1.5, points=outliers.
Industry Proposal

A dose unit which expresses the product quantity in relation to the treated area would be consistent with any kind of spray application (field crops, band, high crops)

The Crop Protection Industry - represented by BASF, Bayer CropScience, Dow AgroSciences, DuPont, Makhteshim Agan and Syngenta - recommends to use LWA as common dose expression unit in efficacy trials for pome fruit for new active ingredients

- Conversion formula are proposed to calculate from LWA to currently used dose expression units and vice-versa
- All relevant parameters will consistently be captured in future field development trials and can be made available in BADs
- The analysis of the industry data sets have shown, that the 95th percentile value is at 20’000 m² for pome fruit. Proposal: max dose rate is set at a LWA of 20’000 m²
- The CP industry proposes to investigate the possible use of LWA in other crops such as other fruit trees, high growing vegetables in glasshouses, grapes and berries
Benefits of a common dose rate expression unit in high crops

- Allowing better and faster comparison and understanding of trial data across different regions, countries and locations, e.g. for the new zonal registration system in the EU
- Avoiding unnecessary repetition of trials; good dose-response curves
- Helping to cope with increasing requirements from regulatory bodies, food chain and trade
- Facilitating communication with and between regulatory bodies
- The dose rate is no more linked to the spray volume, but to the sprayed leaf area of the crop.
- Also suitable for fruiting vegetables in glasshouses, viticulture, berries and other high-growing crops
- The LWA dose expression unit offers the platform for dose adjustments.
- In line with the Sustainable Use Directive and the National Action Plans
Concerns / open questions

• How should old products be handled in case of re-registration using historical data with incomplete crop measurements data. Not all relevant crop parameters were consistently captured in the past. How can we therefore transform dose rates from currently existing dose expression units to LWA.

• How do we tie risk assessments and residues and operator exposure in the registration package which are carried out in rate per ha.

• Acceptance of LWA in GLP residue trials

• How will a LWA label look like

• How will farmers and growers accept LWA
Current status

• Industry proposal was presented in Brussels on October 19, 2011 to the ECPA Efficacy Expert Group (EffEG) and EPPO representatives
  • Actions and next steps defined in the minutes:
    • EPPO has agreed that F. Cors (Belgium) should re-draft the proposed standard. It has been to the Working party. It will now go to the Fungicide/Insecticide Panel, then the General Standards Panel, Working Party and Council for final approval.
    • When the next draft is available it should be sent to Ron and the working group for review and input. The Fungicide/Insecticide panel representatives need to be informed of this.
    • Once agreed then the standard will be published on the EPPO web site. It was also proposed that the work could be published in a peer reviewed journal. An educational video could also be produced - Patrice will discuss potential project funding with ECPA.
    • The group also suggested that work should continue with other potential crops – prioritising stone fruit and grapes.

• EPPO General Standards Meeting, Milan, Italy March 7-9, 2012
  • Topic was controversially re-discussed in depth and a draft of the revised guideline was sent to the countries for consultation.

• 42nd EPPO Working Party Meeting, May 15-16, 2012
  • Draft standard re-discussed and modifications made, but: Dose expression of plant protection products (General Standard PP1/239) has been approved!
Besten Dank für Ihre Aufmerksamkeit!