Dose rate expression in vertical growing crops –
Need for harmonisation from the perspective of the Plant Protection Product Industry

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

R.-B. Toews 1; J.-P. Huby 2; B. Pollmann 3; M. Teichmann 4; P. Schlotter 5; F. Meier-Runge 6

1Bayer CropScience AG; 2Du Pont de Nemours S.A.S.; 3Adama Agriculture B.V.; 4BASF SE; 5Dow AgroSciences; 6Syngenta Agro GmbH
What is this presentation about?

- Introduction
- Industry Proposal
- SWOT analysis
- LWA distribution in orchards/vineyards of different EPPO zones
- Biodossier generation and conversion formula to label rate expressions
- Summary
In the discussion we should keep in mind that...

• We must distinguish between…
  - Dose expression = the unit in which the dose is expressed
  - Dose rate = the quantity of product to be applied
  - Dose rate adjustment = adjustment of the dose rate to the specific field situation

• In view of the new zonal registration system in the EU, the dose expression harmonisation is first of all a help for regulators (efficacy and risk assessment), concentration is not longer sufficient (EPPO PP 1/239(2): Dose expression for plant protection product)

• The Crop Protection Industry proposes to use in the efficacy assessment of vertical growing crops
  - for new registrations and Cat. 4: trials and efficacy assessment with LWA dose expression
  - for reregistrations: existing trials (mainly) with ha or hl expression, no new efficacy assessment (Art 43)
  - critical GAP always with a zonal or EU max rate per ha ground
Why is a common dose rate expression so important?

EC 1107/2009:
3 Regulatory zones
1 Zonal Rapporteur per Zone (zRMS)
and 4 EPPO climatic zones

How can one zRMS evaluate the efficacy for all countries in the zone if the dose expressions are different?
We need a better description than ha ground or hl concentration!
Industry proposal – (treated) Leaf Wall Area

Sprayers deliver the spray liquid containing the product to a predominantly vertical area.

Consequently, the product quantity (dose rate) should not be expressed in relation to the ground area, but to the (treated) leaf wall area.
**Leaf Wall Area (LWA) versus Treated Leaf Wall Area (tLWA)**

<table>
<thead>
<tr>
<th>Leaf Wall Area (m²)</th>
<th>= 2 × <strong>Canopy height</strong> (m) × Ground Area (m²)</th>
<th>Leaf Wall Area (m²) = 2 × <strong>Treated Canopy height</strong> (m) × Ground Area (m²)</th>
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- Actually these are two different variables:
  - Leaf Wall Area (LWA) describes the **Crop**
  - treated Leaf Wall Area (tLWA) describes the **Application**

- Depending on the application equipment used there can be differences between LWA and tLWA.
tLWA > LWA

For applications in the fruiting zone only:
tLWA < LWA
SWOT Analysis of (t)LWA

Strength

• **Simple** system - easy measured parameters
• Considers **seasonal development** of the crop and crop parameters
• Already implemented in BE, indication of support in NL, AT and DE
• Reliability, **consistent** results, good dose response
• Allowing better and faster comparison and **understanding** of trial data across different member states; a must for EU Zonal registration process
• (t)LWA rate can be easily **converted** to national label rate expressions
  - trial by trial individually
  - the resulting target rate generally using assumptions
SWOT Analysis of (t)LWA

Weakness

- **Simple** system – (t)LWA model may not to be the best model for crop adapting spraying, but it is far better than rate expressions not considering the crop structure
- Not a good fit for **old** traditional orchards
- Additional information reflecting **regulatory limitations** (dose/ha ground) is needed for the cGAP and for the farmers’ guidance and labels, but not for dose definition trials
SWOT Analysis of (t)LWA

Opportunities
• Can be used as platform for dose adjustment
• Helping to cope with increasing requirements from regulatory bodies, food chain and trade.
• Applicable to reduce variability in other registration sections (residues)
• Facilitating communication with and between regulatory bodies.
• Allows targeted sprays, e.g. Botrytis in grapes or insects cluster in crops
• In line with the Sustainable Use Directive and the National Action Plans.

Threats
• Standardization in measurements and reporting of relevant parameters needed
• Old GEP trial reports may not contain all crop parameter information (treated canopy height) or reported parameters may have been measured incorrect
• Trial sites may differ in their crop parameter from commercial practice
Industry Data - LWA PER EPPO ZONE and BBCH (apple & pear)

One data point per application, data from 2009 to 2015
Industry Data - LWA PER EPPO ZONE and BBCH (cherry & plum)

One data point per application, data from 2009 to 2016
Industry Data - LWA PER EPPO ZONE and BBCH (apricot, nectarine and peach)

One data point per application, data from 2008 to 2016
## Industry Data - LWA PER EPPO ZONE and BBCH (grapes) Central Reg zone

<table>
<thead>
<tr>
<th>Median of LWA by Zone, Training / Country / Growth period</th>
<th>00-08 Bud &amp; leaf growth</th>
<th>61-70 Flowering</th>
<th>71-74 Fruit set</th>
<th>75-99 Berries</th>
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One data point per application, data from 2013 to 2015
## Industry Data - LWA PER EPPO ZONE and BBCH (grapes) South Reg zone

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<th>61-70 Flowering</th>
<th>71-74 Fruit set</th>
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One data point per application, data from 2013 to 2015
### Biodossier generation is linked with trial execution

**Past:**
- Reporting quality from today's perspective not always perfect
- Dose in trials expressed heterogeneously (e.g. per ha ground or hl)
- Trials conducted on sites with variable (t)LWA with variable water volumes
- Trials are summarized based on local dose expression
- MED defined on local dose expression
- Endpoint calculation and risk assessment considering this rate per ha ground
- Label definition using conversions into national dose expression

**Future:**
- Improved reporting quality and consistent use of harmonized terms
- Dose in trials expressed per 10,000 m² tLWA
- Trials conducted on sites with variable (t)LWA with variable water volumes
- Trials are summarized based on dose rate per 10,000 m² tLWA
- MED defined per 10,000 m² tLWA
- Endpoint calculation and risk assessment considering a realistically relevant, high rate per ha ground
- Label definition using conversions into national dose expression or tLWA
### Conversion of tLWA to other dose models

#### Parameter to be recorded

- row spacing (m)
- treated canopy height (m)
- ground area (m²)
- applied spray volume (SPV, L per ha)
- applied dose (x, kg or L per tLWA)
- tree or foliage width (m) for conversion to TRV

#### Conversion Formula

| Conversion to rate per ha ground area | $\text{rate}_{GA} = \frac{x \cdot tLWA}{10000}$ |
| Conversion to rate per hl            | $\text{rate}_{HL} = \frac{x \cdot tLWA}{SPV \cdot 100}$ |
| Conversion to rate per ha ground area and per m foliage height (FH) | $\text{rate}_{FH} = \frac{x \cdot 2}{\text{row distance}}$ |

Source: Syngenta Crop Protection, 2011
Example for easy conversion of the target rate

- E.g. 1 L/10,000 m² tLWA in pome fruit
  Endpoints and RA cover a max rate for the zone of 1,8 L/ha ground

- Commercially relevant pome fruit orchards in country X vary from 7000-15000 m² tLWA
  - Recommended rate range: 0,7 – 1,5 L/ha ground

- Mean (commercially relevant) tLWA in country X = 12,000 m²
  - Recommended rate: 1,2 L/ha (as an average value)

- Farmers apply normally water volumes of max 1000 L/ha in country Y
  - Recommended rate: 180 ml/hL
  - Or recommended rate range: 100-200 ml/hL

… but also: Do not exceed 1,8 L/ha!
Transfer from efficacy assessments to label rates

Simplest approach – if legally accepted:

- Labels display the rate per tLWA (as validated in BAD) plus a max ha ground rate (as validated in other sections)

or

As in the past:

- Labels display the rate using national expressions, this dose rate was converted from tLWA
Summary

• In view of the new zonal registration system in the EU, the dose expression harmonisation in efficacy assessments is first of all a help for zonal rapporteur regulators who need to assess on behalf of several counties with potentially different dose expressions.

• 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, vertical crops).

• The Crop Protection Industry proposes to use (t)LWA as common dose expression unit in efficacy trials and Biological Assessment Dossiers for most 3D crops for new active ingredients and new projects.
Summary

• All relevant parameters will consistently be captured in future field development trials and will be made available in BADs. With this information it is possible on single trial basis to convert the dose rate

• Conversion formula are proposed to calculate from (t)LWA to currently used dose expression units

• The Crop Protection Industry needs planning security and clarity on transition and implementation timeline as well as clarity on validity of existing risk assessments and existing efficacy trial data
Questions and comments?