The Need to Harmonize Dose Expression in the Zonal Efficacy Evaluation

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OVERVIEW

1) Introduction
2) Triggers for Harmonization
3) Factors of Influence
4) Use of Terms & Definitions
5) Conclusions
(1) Introduction

**TOPIC**

Workshop on
**Harmonized Dose Expression**
for the **Zonal Evaluation** of Plant Protection Products in High Growing Crops

**KEY OBJECTIVE**

„Harmonization“

**MAIN FOCUS/MAIN TERMS**

„Dose Expression“ & „Zonal Efficacy Evaluation“
(1) Introduction

„Dose Expression“ & „Zonal Efficacy Evaluation“

= the dose of a plant protection product (PPP; in kg or L) linked to
a certain reference unit.

→ Reference units mainly used in the EU
ha ground, spray volume (concentration in %), m canopy height (mCH),
ha leaf wall area (LWA), etc.

→ The dose expression (reference unit) in the evaluation approach clearly
influences the accuracy of results and their value for registration and local
practice.
(1) Introduction

„Dose Expression“ & „Zonal Efficacy Evaluation“

EPPO standard PP1/239(2)
„Dose expression for plant protection products“

→ **Reference units** listed and discussed for high growing crops:

- ha ground, m canopy height (mCH), tree row volume (TRV), ha leaf wall area (LWA), spray volume (concentration in %), plant row etc.

→ **Interconvertability between dose expressions is recommended**
(1) Introduction

„Dose Expression“ & „Zonal Efficacy Evaluation“

- Regulation (EC) 1107/2009
- Collective evaluation of trials within the EPPO zones

→ Zonal Efficacy Evaluation

→ National Efficacy Assessment
→ National Registration Procedure and Labeling

→ Advice for Farmers
(1) Introduction

Reference units /parameters in trial reports

Zonal efficacy evaluation based on a harmonized dose expression

RR & final conclusion

dRR

BAD

trial reports

Farmers´ instructions

Mutual recognition

National assessment, dose expression for registration and labeling

National tasks

Zonal tasks

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(1) Introduction

National tasks →

hardly to be harmonized

Zonal tasks →

OUR FOCUS, harmonization targeted

Farmers’ instructions

Mutual recognition

National assessment, dose expression for registration and labeling

Zonal efficacy evaluation based on a harmonized dose expression

Reference units /parameters in trial reports

Responsibility of:
- National registration authorities;

Influenced by:
- National legislation;
- Local practice;

RR & final conclusion

dRR

BAD

trial reports
(2) Triggers for Harmonization

- of the „Dose Expression“ for the „Zonal Efficacy Evaluation“

I. Correctness of the efficacy evaluation within the zonal assessment

II. Validity of results for all MS

III. Easy convertability of zonal conclusions to

   → national dose expressions
   → and registration practice
(2) Triggers for Harmonization

I. Correctness of the efficacy evaluation in the zonal assessment

*a current example: dose is given in kg PPP/ha ground*

Arable crops:
Ground area = Area of application

High growing crops:
Area of application ≠ Ground area

= Leaf wall area (LWA)
(2) Triggers for Harmonization

Venturia inaequalis in apples, applied for the Maritime EPPO Zone

<table>
<thead>
<tr>
<th>Area of application in m²/ha ground</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min</td>
<td>10.000</td>
</tr>
<tr>
<td>Max</td>
<td>10.000</td>
</tr>
<tr>
<td>Diff</td>
<td>0</td>
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<tr>
<td>Mean</td>
<td>10.000</td>
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<tr>
<td>SD</td>
<td>0</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>n = 67</th>
</tr>
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<tbody>
<tr>
<td>Min</td>
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<tr>
<td>Max</td>
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<td>Diff</td>
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<tr>
<td>Mean</td>
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<tr>
<td>SD</td>
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</tbody>
</table>
(2) Triggers for Harmonization

1. Dose in kg or L per ha ground
2. Inhomogeneity of crop structure
3. Efficacy values not discussed in regard of the real application area (BAD, dRR, RR)

### Minimum effective dose:
- cannot be seriously calculated

### Efficacy:
- risk of low control values in orchards with high LWA
- risk of overdosing in orchards with low LWA with an unnecessary risk for humans and environment

### Phytotoxicity:
- risk of phytotoxic effects in orchards with low LWA

### Resistance:
- risk of resistance development in orchards with high LWA

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**Table: Area of application**

<table>
<thead>
<tr>
<th></th>
<th>Area of application in m²/ha ground</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min</td>
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<td>15715</td>
<td>120</td>
</tr>
<tr>
<td>SD</td>
<td>3244</td>
<td>21</td>
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</tbody>
</table>

n = 67
II. Validity of results (RR & its conclusions) to all MS

- *The RR should provide all necessary information for the following national registration and labeling.*

- Is the accuracy of the evaluation sufficient for the following national assessments, for registration and labeling in the cMS?
- Which application areas (crop structures) were considered?
- Which crown height was tested?
- Which spray volumes are proved?
(2) Triggers for Harmonization

III. Easy convertability of zonal conclusions to national dose expressions and registration practice

- Is all information provided to convert to other dose expressions?

  - Has the evaluation been calculated with the most accurate dose expression?
(2) Triggers for Harmonization

I. Correctness
II. Validity
III. Convertability

To achieve this →

- **Data calculation** (= zonal efficacy evaluation) needs to be based on the most accurate dose expression used by MS.

- **Zonal conclusions** should include information on parameters which define other reference units used by MS.

- Thereafter, **conversion** to other dose expressions is possible.
(3) Factors of Influence

Major factors influencing the selection of a "Dose Expression" in the "Zonal Efficacy Evaluation" are diverse.

I. **Legal requirements**

II. **Local conditions of the MS**

III. **Applicants decision & responsibility**
(3) Factors of Influence

I. **Legal requirements:**

  - Zonal evaluation (Collective evaluation of trials within EPPO zones)
  - Mutual recognition

- National legislation
  - dose expressions used in registration and labeling

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**Not to be discussed!**
(3) Factors of Influence

II. Local conditions of the MS:

- Inhomogeneity of crop structure in orchards, vineyards etc.

- Diversity of technical equipment

  - Major factors of influence
  - Potential for high diversity
  - Harmonization unfeasible

Diversity is the common fundament

Facing this challenge!

- National practice in efficacy evaluation & expression of dosing

  - Potential for high diversity

Diversity to be questioned & Harmonization targeted

To be considered!

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III. **Applicants decision & responsibility:**

- Technical development of a PPP
- Diversity of dose expressions actually used in trial reports
- Availability of data/parameters in single trial reports

**Factors of Influence:**
- Major factors of influence
- Potential for high diversity
- Harmonization feasible

Diversity to be questioned & Harmonization targeted
(3) Factors of Influence

**Summary:**

- Inhomogeneity of crop structures
- Diversity of technical equipment

- National practice in efficacy evaluation & expression of dosing
- Diversity of dose expressions actually used & Availability of data/parameters in single trial reports

→ to end up with →

a harmonized „Dose Expression“ for the „Zonal Efficacy Evaluation“
(4) Use of Terms & Definitions

- Dose expression
- Dose / Dose rate
- Reference unit

- LWA
  - How is it calculated?
  - Is LWA similar to the treated area?

- Tree height
- Canopy height
- Which one reflects the treated height?

- Zonal Efficacy Evaluation
- National Efficacy Assessment
- Registration and Labeling
- Advice for Farmers

- Dose expression
- Dose adjustment
Dose expression

VERSUS

Dose adjustment

Dose expression = the dose of a plant protection product (PPP; in kg or L) linked to a certain reference unit.

A maximum dose may be applied

→ at all stages of the crop OR

→ at the latest BBCH stage
→ at the BBCH stage with the largest application area...

Dose adjustment
(4) Use of Terms & Definitions

PP1/239(2):

“It should also be emphasized that dose adjustment is a separate process by which the dose applied is reduced or increased in accordance with canopy size, density and climatic factors to obtain minimum variation in deposit across a wide range of crop structures.”

In general:

Dose adjustment = Reduction of the target dose in respect to smaller application area e.g. due to early BBCH stages

Zonal task? OR Local practice?
Open questions:

- Do dose adjustments according to local practice affect trial results?
- How to consider dose adjustment in the evaluation procedure?
- Are current dose expressions able to display varying application areas?
- Is harmonization feasible?

Zonal task? OR Local practice?

To be discussed!
Decisions to be made!
(5) Conclusions

Triggers
I. Correctness
II. Validity
III. Convertability

Factors
I. Legal requirements
II. Local conditions of the MS
III. Applicants decision & responsibility

Harmonization is needed!

To be considered!

To be aware of their definitions!

Use of Terms
(5) Conclusions

Key Objective

"Harmonization"

Major tasks

I. Become aware of the current challenges and needs in the zonal efficacy assessment of high growing crops.

II. Specification of the most appropriate dose expression for zonal efficacy evaluation.

III. Exact definition of used terms.

IV. Exact definition of parameters to be measured in the field, and precise instructions to measure them.
Further Questions

a. If parameters are missing in new trial reports so that certain dose expressions cannot be used, what is still acceptable?

b. How to calculate plot size in the individual trial reports and the dose to be applied per plot?

c. Does the spray volume need to be adjusted to the LWA?

d. May a harmonized EXCEL based tool be helpful for the conversion of different dose models?
Further Questions

e. When do you consider dose adjustment necessary in practice?

f. Would it be possible to develop models of dose gradation (for dose adjustment) for individual crops?

g. How do you evaluate ‘old’ efficacy studies without having sufficient information on crop structures e.g. during the renewal of PPPs?

h. How should a useful conclusion look like so that information needed for national assessments and registration is adequately included and of high value?

i. ..........
- to improve & simplify national tasks!

It’s time to harmonize zonal tasks! -
- pleasant debating atmosphere
- lively and constructive discussions
- convincing results