

*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*

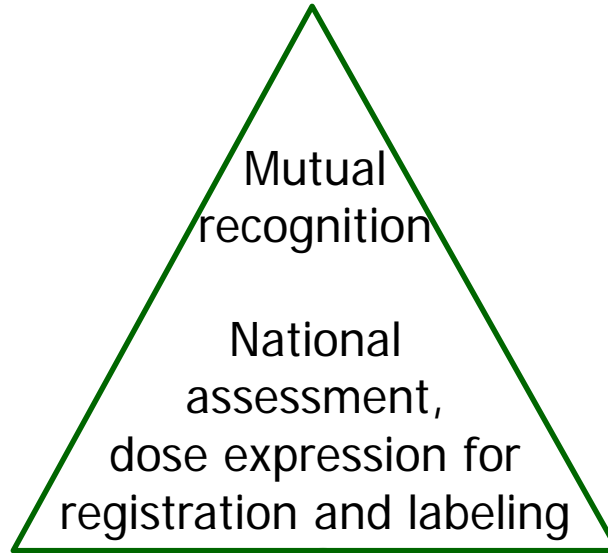
→ *Advice for Farmers*

# (1) Introduction

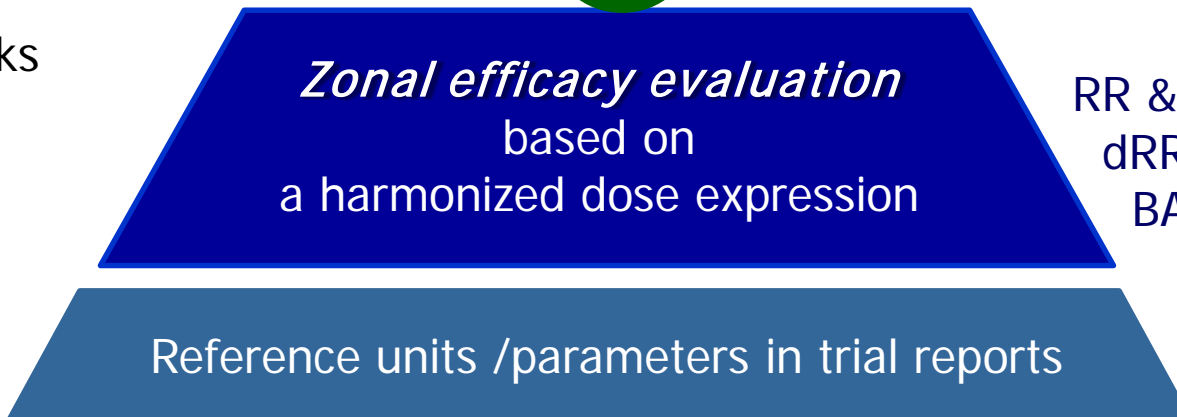


Farmers' instructions

National tasks



Zonal tasks



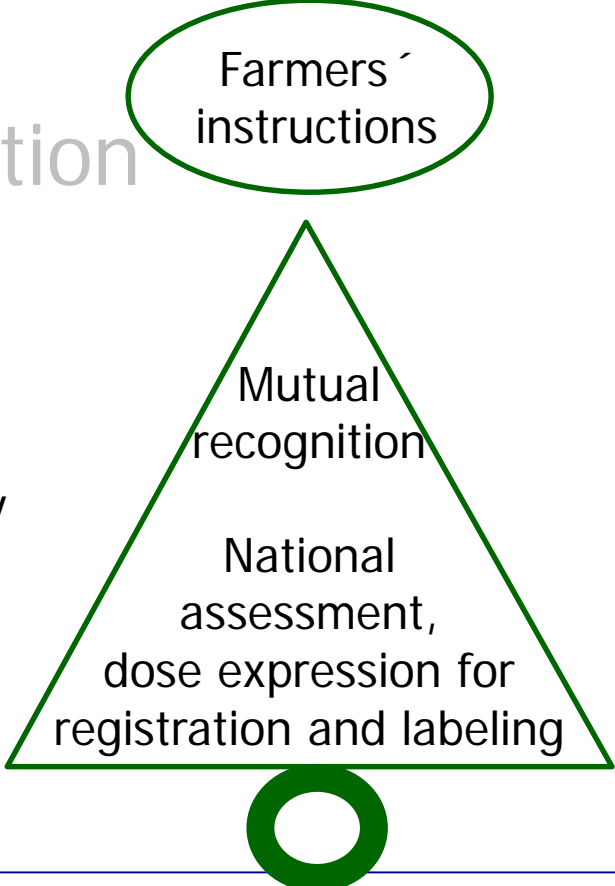
RR & final conclusion  
dRR  
BAD

trial reports

# (1) Introduction

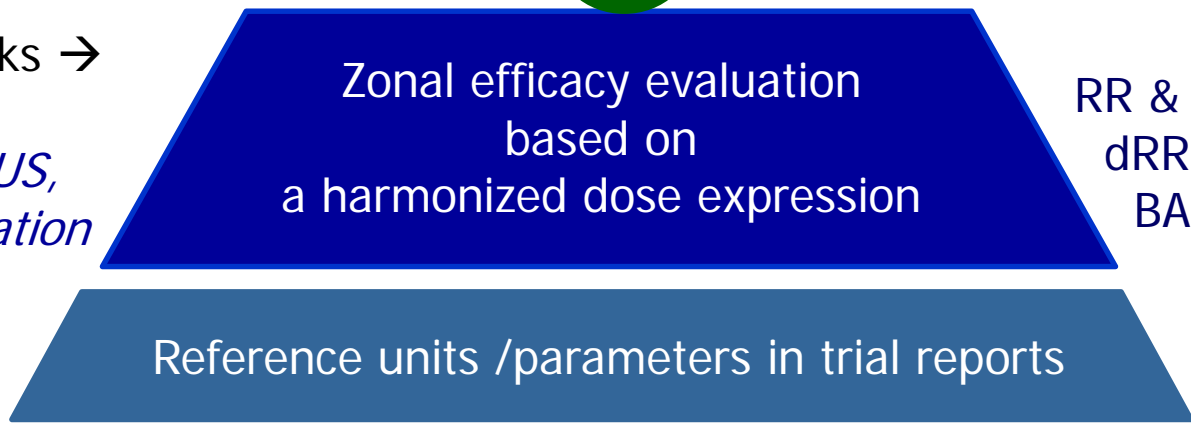


National tasks →  
*hardly to be harmonized*



- Responsibility of:
- National registration authorities;
- Influenced by:
- National legislation;
  - Local practice;

Zonal tasks →  
*OUR FOCUS, harmonization targeted*



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  $\neq$  Ground area



## (2) Triggers for Harmonization



Picture: Katharina Böhm

|      | Area of application in<br>m <sup>2</sup> / ha ground | % |
|------|--|---|
| Min  | 10.000   |   |
| Max  | 10.000   |   |
| Diff | 0  |   |
| Mean | 10.000   |   |
| SD   | 0  | 0 |

*Venturia inaequalis* in apples, applied for the Maritime EPPO Zone



Picture: Ingrid Langer

|        | Area of application in<br>m <sup>2</sup> / ha ground | %   |
|--------|--|-----|
| n = 67 |  |     |
| Min    | 10.000   | 100 |
| Max    | 22.000   |     |
| Diff   | 12.000   | 120 |
| Mean   | 15.715   |     |
| SD     | 3.244  | 21  |

## (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)

| n =67 | Area of application in<br>m <sup>2</sup> / ha ground | %   |
|-------|--|-----|
| Min   | 10000  | 100 |
| Max   | 22000  |     |
| Diff  | 12000  | 120 |
| Mean  | 15715  |     |
| SD    | 3244   | 21  |

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

## (2) Triggers for Harmonization



### 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 →

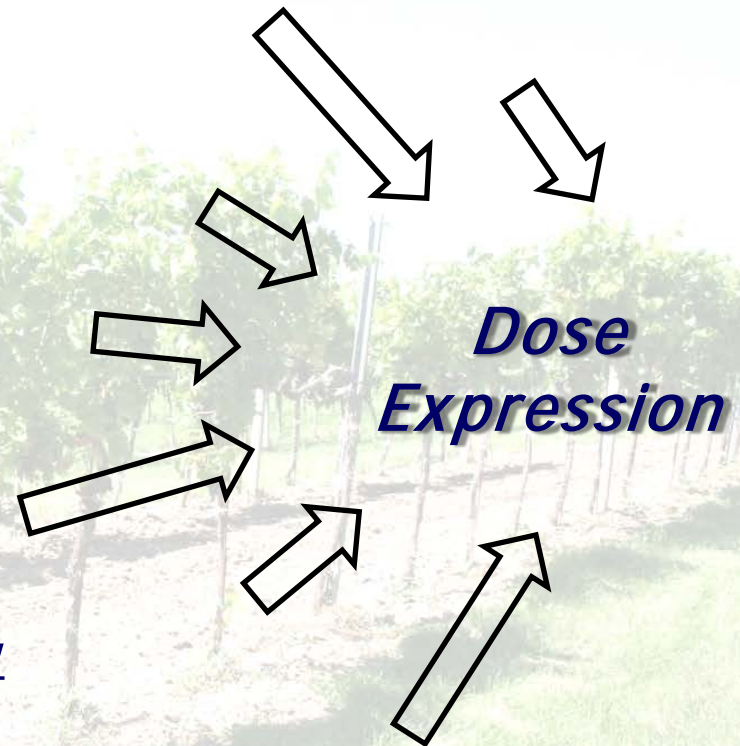
- *Data calculation* (= zonal efficacy evaluation) needs to be based on the *most accurate dose expression* used by MS.
- *Zonal conclusions* should include information on parameters which define other reference units used by MS.
- Thereafter, *conversion* to other dose expressions is possible.

To be harmonized  
To be agreed

# (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:

- Regulation (EC) 1107/2009,  
Commission Regulation (EC) 545/2011 etc.

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

- Mutual recognition

common fundament

- 
- National legislation

MS specific restrictions

- dose expressions used in registration and labeling

*Not to be discussed!*

# (3) Factors of Influence



*To be considered!*

## 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

- 
- National practice in efficacy evaluation & expression of dosing

- Potential for high diversity

Diversity to be questioned & Harmonization targeted

*Facing this challenge!*

# (3) Factors of Influence



## 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

*To be considered!  
&  
Harmonization to be promoted!*

- 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

Diversity is the common fundament

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

Diversity to be questioned & Harmonisation targeted

→ 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

.....

.....

.....

## (4) Use of Terms & Definitions

Dose expression

*VERSUS*

Dose adjustment



= 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?*

## (4) Use of Terms & Definitions



### 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?

To be discussed!  
Decisions to be made!

*Zonal task? OR Local practice?*



# (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.

## (5) Conclusions



### *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?

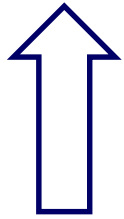
## (5) Conclusion



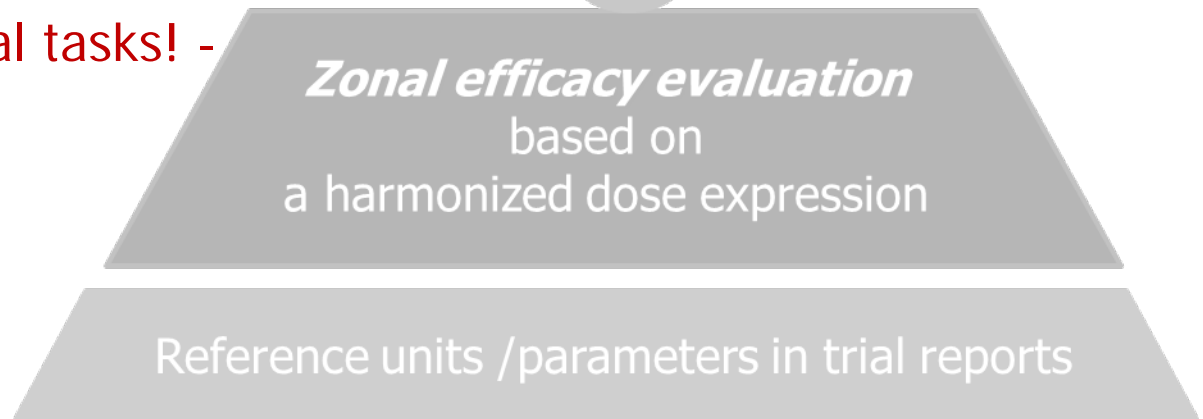
### *Further Questions*

- 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

