The Dose Expression of Plant Protection Products - A Harmonization Approach

Ingrid Langer

Institute for Plant Protection Products

AGES – Austrian Agency for Health & Food Safety, Vienna;

- *on behalf of* - EPPO – European and Mediterranean Plant Protection Organisation

Triggers (1) for the Harmonization Attempts

In arable crops:

treated area = ground area

	Treated area in m^2/ ha ground	%
min & max	10000	
Diff	0	
mean	10000	
std	0	**0**

In high growing crops:

treated area ≠ ground area

n = 67	Treated area m^2/ ha ground area	%
min	10000	
max	22000	
Diff	12000	
mean	15715	
std	3244	**21**

Triggers (2) for the Harmonization Attempts

Regulation (EU)1107/2009

Zonal assessment procedure

across countries

⇔

Inhomogenity of high growing crops

in Europe,

within EPPO-Zones,

and even within single countries…

⇩

Different distances between rows

+

Different trainig systems (leaf wall areas)

=

Different application areas

Triggers (3) for the Harmonization Attempts

Current consequences for the assessment and the agricultural practice :

Without reference to the treated crop area (in high growing crops this is the treated leaf wall area)

→ the Minimum Effective Dose cannot be seriously deduced.

Efficacy: Risk of low control values in plants with high LWA;

Possibility of overdosing in plants with low LWA bearing an unnecessary risk for humans and environment;

Resistance: Risk of resistance development in plants with high LWA;

Phytotoxicity: Risk of phytotoxic effects in plants with low LWA.

Good reasons to talk about it!

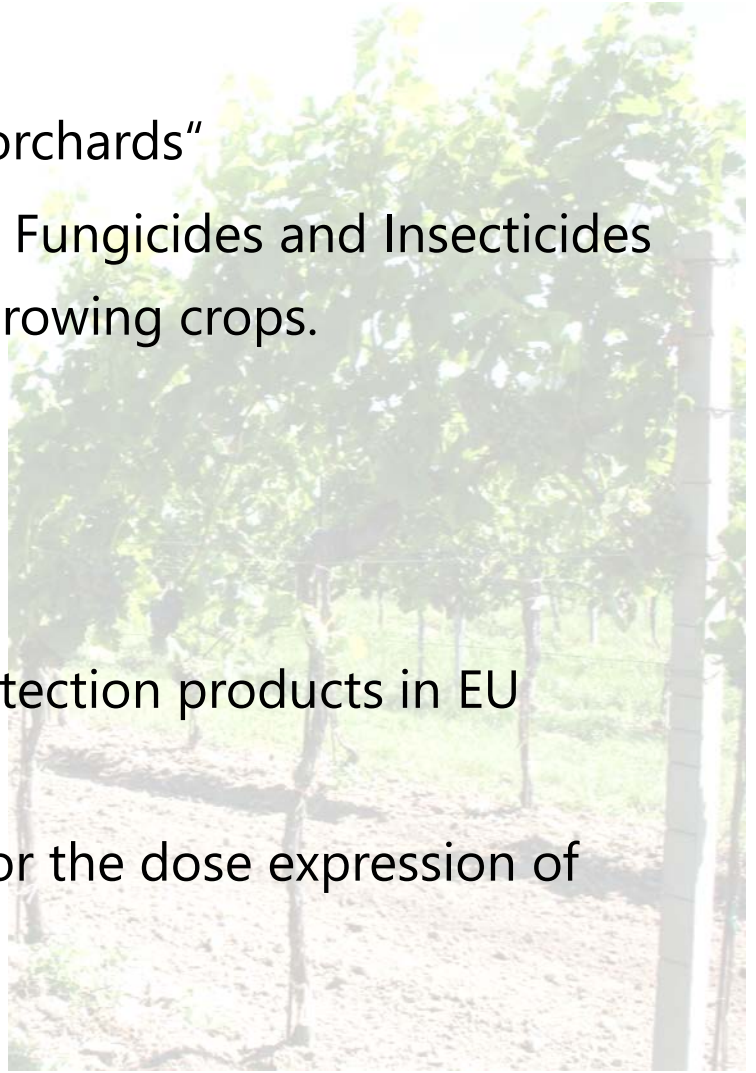
Early Attempts of Harmonization

1997:

"A new method to determine spray volume and product quantity in orchards"

CH document presented at the EPPO Panel on Efficacy Evaluation of Fungicides and Insecticides

→ Initializing work on harmonization of dose expression in high growing crops.



1998:

"EPPO document no. 98-6960"

AT comment on the current situation of the registration of plant protection products in EU orchards

→ asking EPPO to make efforts towards a harmonized guideline for the dose expression of plant protection products in orchards.

Early Attempts of Harmonization

2001:

"EPPO document 01/8780"

EPPO ad hoc meeting on the Expression of Dose Rates → Agreements

- there is a **need** to harmonize expression of the dose in all EPPO countries for all crops;
- *the same expression of the dose should be used in all trials, in trial reports, on labels & should be suitable as input for environmental risk assessments;*
- the **concentration** of the liquid is considered unsatisfactory;
- the ideal method for expression of the dose **should take account of the total leaf area** in relation to the field area …
- a single system of expression of the dose could not be agreed.

The EPPO Standard

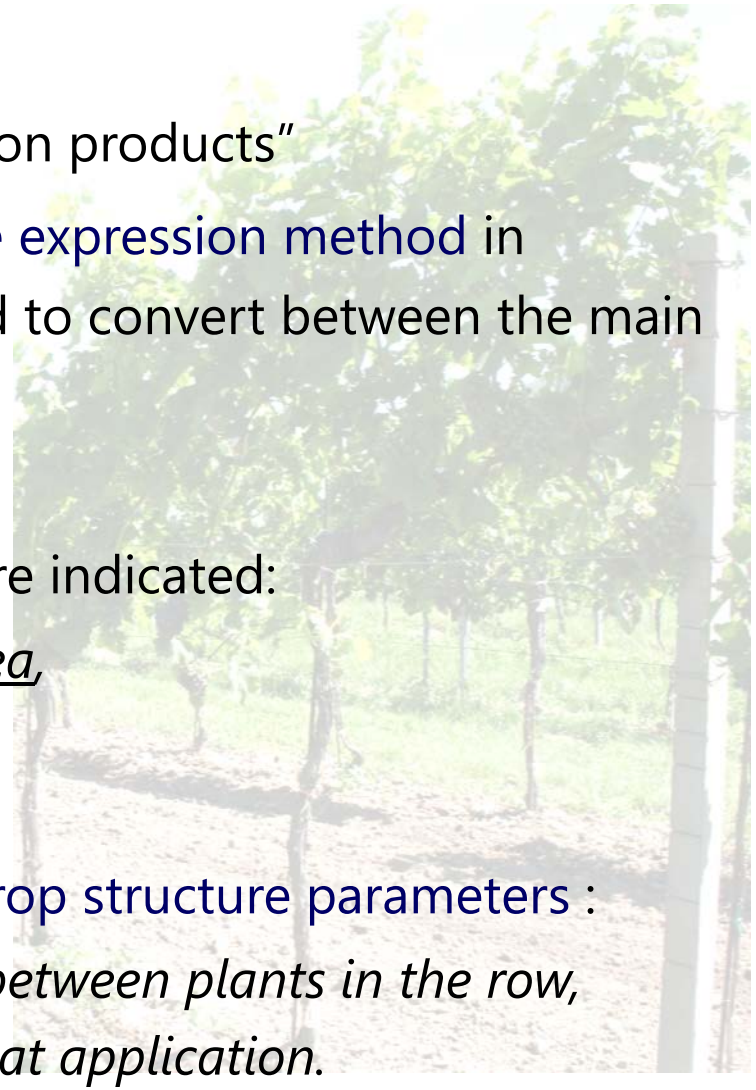
2005/2012:

"EPPO standard PP1/239(1) & (2) Dose expression for plant protection products"

- …'per treated leaf wall area unit' (LWA) is becoming a common dose expression method in 3 dimensional crops. However, this standard also provides a method to convert between the main country dose expression methods;

- for orchards, hops, and vineyards the following dose rate systems are indicated:
  ".....kg or L per m^3 of Tree Row Volume, kg or L per ha of Leaf Wall Area, kg or L ha^{-1} and per m tree height, kg or L per 100 m of plant row....";

- to interconvert between these systems, it is necessary to measure crop structure parameters :
  cropping system (single or multiple rows), distance between rows & between plants in the row, treated foliage height & mid-width of the crown, BBCH growth stage at application.



EPPO Workshop hosted by AGES/ AT

2016:

AGES hosting the **EPPO Workshop** (October 18th -20th, 2016)

"EPPO Workshop on harmonized dose expression for the zonal evaluation of plant protection products in high growing crops."

86 participants from 18 EPPO countries,

35 – National Regulatory Authorities,
Research Institutes & Universities,

29 – from Crop Protection Companies,

20 – from Consultants.

EPPO Workshop hosted by AGES/ AT

"EPPO Workshop on harmonized dose expression for the zonal evaluation of plant protection products in high growing crops."

FOCUS:

- dose expression

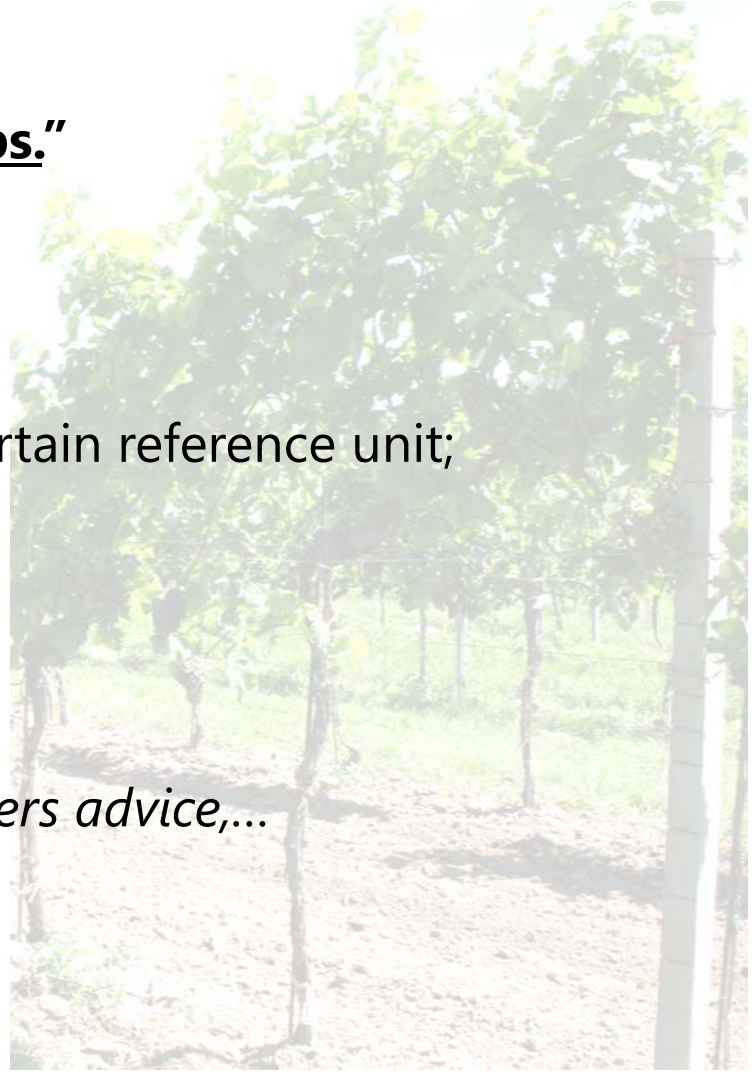
= the dose of a plant protection product (PPP; in kg or L) linked to a certain reference unit;

not in the focus: the dose itself, dose adjustment,…

- efficacy evaluation in the zonal system

not in the focus: national assessments, registration affairs, labeling, farmers advice,…

- high growing crops



EPPO Workshop - General Conclusions

Conclusions were worked out in a final plenary session and follow the outcome of four individual working groups: Grapevine - Pome fruit - High growing vegetable crops - Citrus

- **Leaf Wall Area (LWA) / *treated Leaf Wall Area (tLWA) / treated crop area***
  - was agreed as an appropriate dose expression for plant protection products in pome fruit, grapevine & high growing vegetables;

- **Kg or L/ha ground**
  - is not to be used in the zonal efficacy evaluation of plant protection products as it is not linked to any crop structure parameters;
  - but, to be reported additionally in the GAP table;

EPPO Workshop - General Conclusions

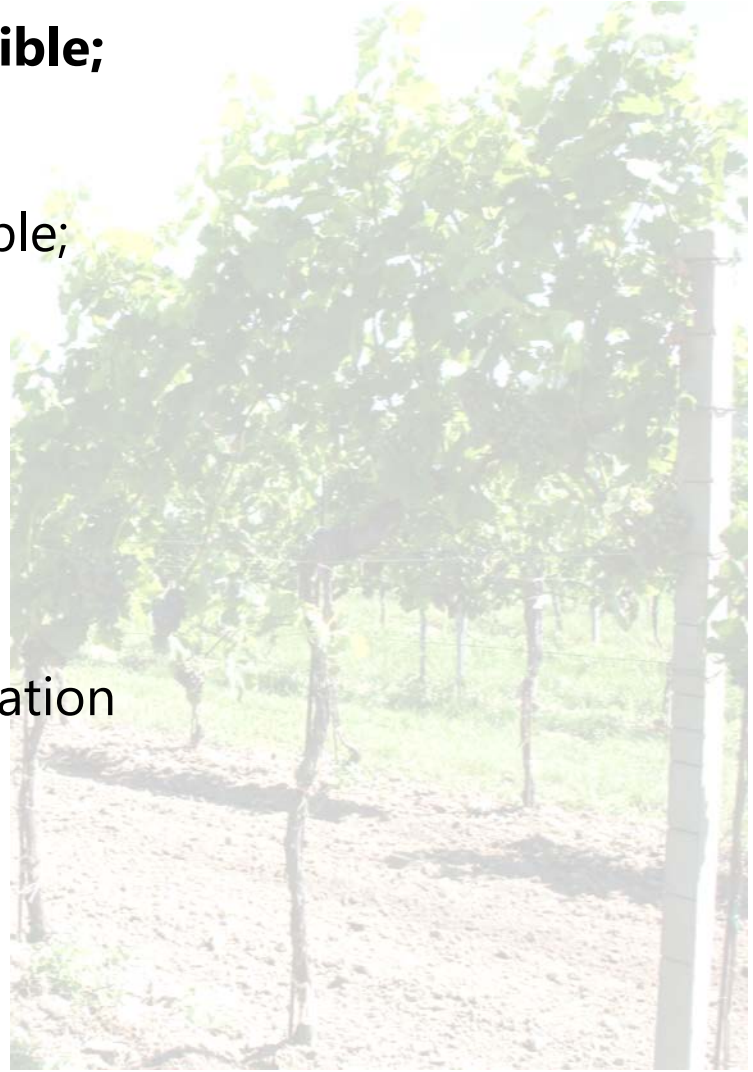
- **Conversion of different dose expressions should always be possible;**

- All relevant **crop parameters** should be measured and made available;

- **Two different situations should be distinguished:**

  (1) crops that form ‘walls’ and (2) ‘globular (isolated) trees’;

  For ‘globular trees’ further data should be collected to enable calculation of canopy width (the 3rd dimension).



EPPO Workshop - General Conclusions

- A **summary table has to be added to the BAD** including the dose ranges used in each trial for the different dose expressions (see EPPO Standard PP 1/239 Dose expression for plant protection products);

- For other dose expressions, **proposals should be drafted by the applicant** and **included in the draft Registration Report** (dRR);

EPPO Workshop - General Conclusions

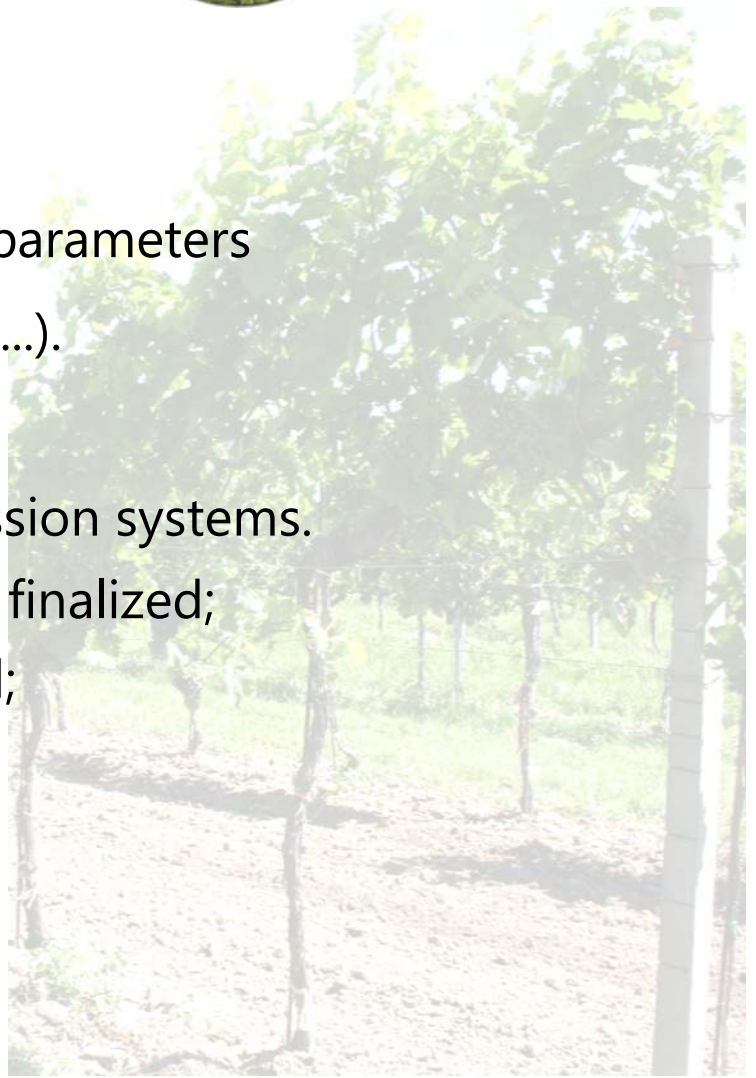
- Clear **definitions** of the terms are needed;
- A guidance on how to **measure** in the field should be prepared;
- The **revision of EPPO Standard PP 1/239** will be on the agenda of the EPPO Panel on General Standards. It will also include a proposal to change the scheme “Conversion of different dose models for high crops”;
- Any proposal for further harmonization should be discussed and validated by the **European efficacy evaluators**;

EPPO Workshop – Following Working Groups

- Two ***ad-hoc* Working Groups** have been established by EPPO:

  - on a glossary of terms and on a guide for measurement of crop parameters (treated LWA *versus* LWA, crop height *versus* treated crop height,...).

  - on examples for dose conversion from LWA to other dose expression systems.
  - an Excel Tool for dose conversions will be further developed and finalized;
  - further information on national crop parameters will be collected;



https://www.eppo.int/MEETINGS/2016_meetings/wk_dose_expression

The EPPO Workshop – Results

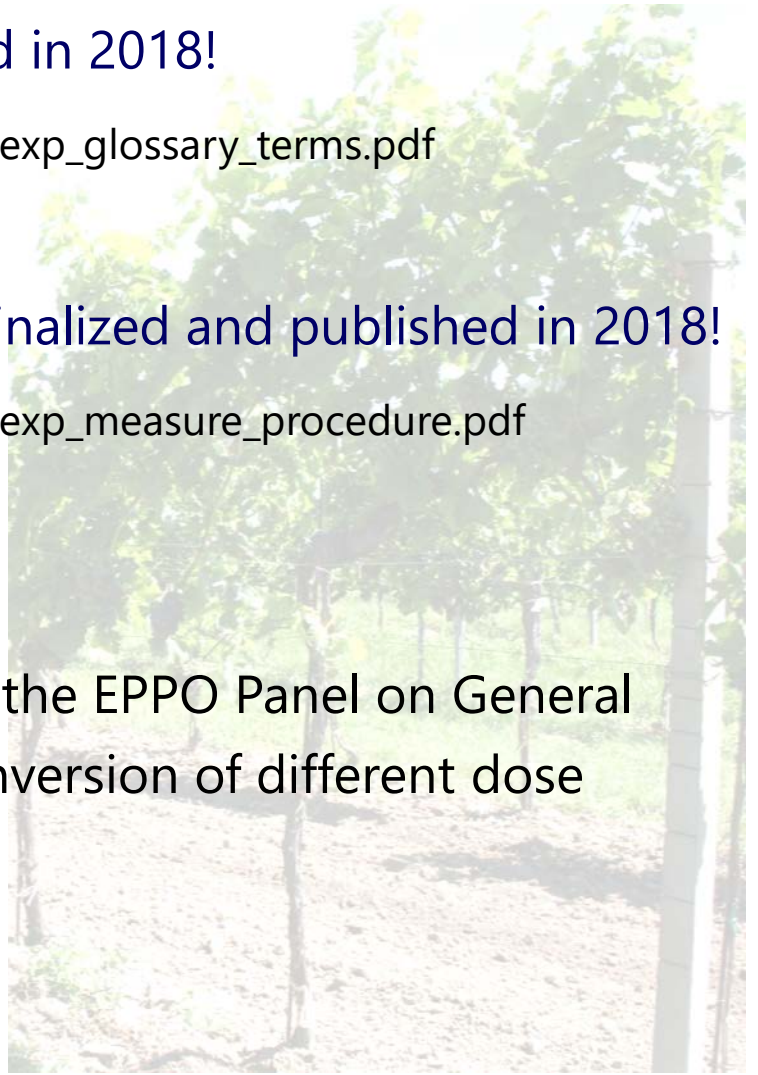
- Clear **definitions** of the terms are needed → finalized and published in 2018!

https://www.eppo.int/media/uploaded_images/ACTIVITIES/plant_protect_products/Dose_exp_glossary_terms.pdf

- A guidance on how to **measure** in the field should be prepared → finalized and published in 2018!

https://www.eppo.int/media/uploaded_images/ACTIVITIES/plant_protect_products/Dose_exp_measure_procedure.pdf

- The **revision of EPPO Standard PP 1/239** will be on the agenda of the EPPO Panel on General Standards. It will also include a proposal to change the scheme "Conversion of different dose models for high crops" → starting in Dec. 2018!



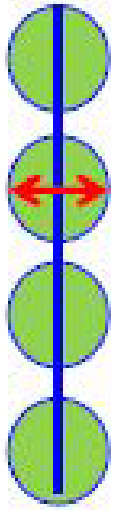
The EPPO Workshop – Results

Terms	Definitions
Crop related terms	
High growing crops	Term for crops such as pome fruit & stone fruit ("top fruit"), small fruit (except for strawberry; e.g. raspberry, blackberry, currants,), grapevine, hop, citrus fruit, nut fruit, olives, but also some vegetables (i.e. tomato, pepper, aubergine, cucumber) and ornamentals (e.g. roses, alley trees) **grown vertically** in open field or in green houses. The foliar PPP applications (other than herbicides) in high growing crops are normally not sprayed towards the ground as is the case for other field crops, but sidewise and/or upwards.
Wall forming crops or **Wall crops**	Terms for high growing crops with a linear ground projected area without significant gaps along the row. E.g. super intensive crops of olives, apple, pear, grapevine.
Globular crops	Terms for high growing crops with elliptical or round ground projected area, with or without gaps in the row between the single plants resp. canopies. E.g. citrus, olives, stone fruits, nut fruits, persimmon, pomegranate.
Foliage height (FH) Unit: m	Distance from the lowest leaves / fruits to the plant top, excluding the stem area.

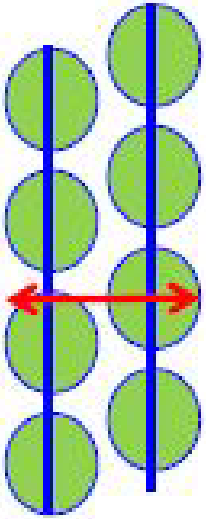
The EPPO Workshop – Results

Definition of **Mid Width of the Canopy**

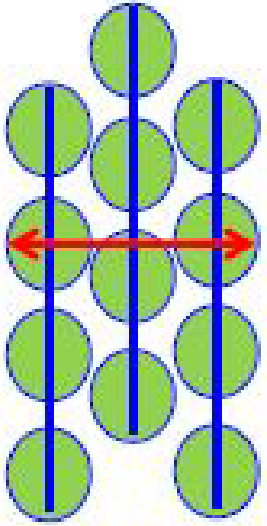
Single Row



Double Row



Multiple Row



Average **Plant Diameter** should be taken at mid-height of the canopy height (do not take into account extreme shoots in height and in width which could impact the total canopy height).

European Efficacy Evaluators

- Any proposal for further harmonization should be discussed and validated by the **European efficacy evaluators** → ongoing approach at the yearly European Efficacy Evaluators Meeting!

  6th European Efficacy Evaluators Meeting in Athens 2017;

  7th European Efficacy Evaluators Meeting in Dublin in 2018;

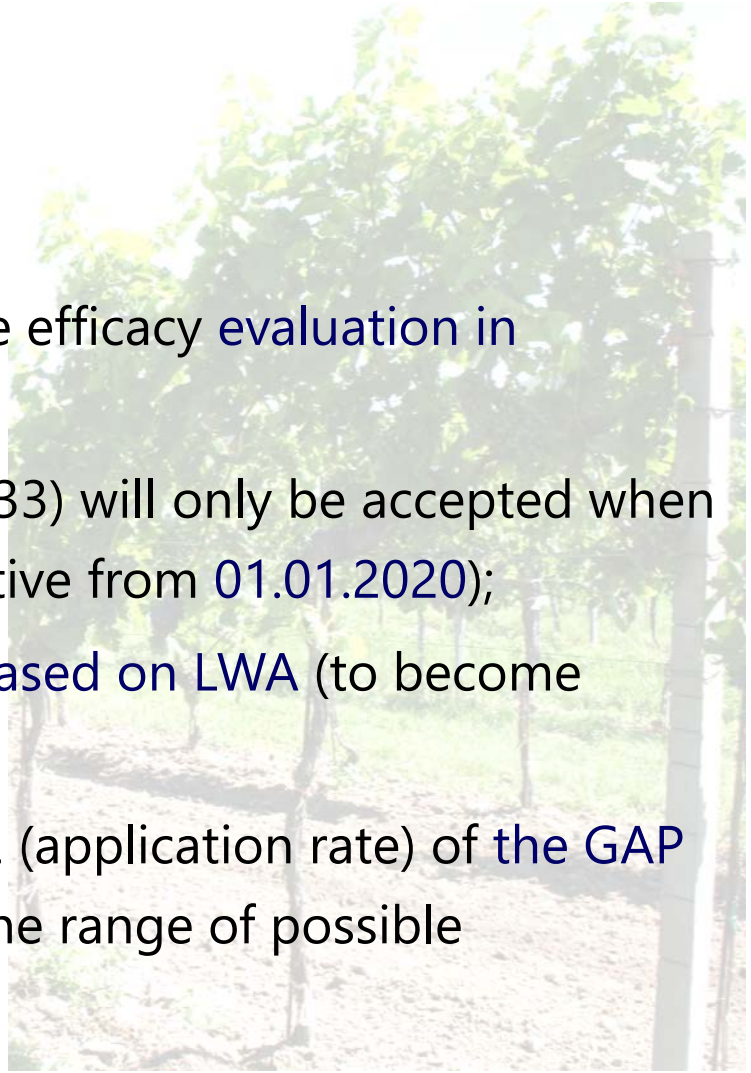
- Agreements regarding the dose expression in high growing crops were made →
  for the **central registration zone** AND
  put forward to be agreed by the central zone steering committee (**czsc)**;

European Efficacy Evaluators

6th European Efficacy Evaluators Meeting in Athens 2017;

- for the application for new products in the central zone:

- The leaf wall area (LWA) concept should first become effective in the efficacy evaluation in grapevine, pome fruit and high growing vegetables;
- In these crops, application dossiers for new products (under Article 33) will only be accepted when trials were planned and carried out based on LWA (to become effective from 01.01.2020);
- Accordingly, the respective trials must be planned and carried out based on LWA (to become effective from 01.01.2018);
- The LWA dose rate shall be added in column 14 (remarks) or 10 - 12 (application rate) of the GAP table. It is restricted by the maximum rate per ha ground area and the range of possible concentrations resulting from columns 10-12 of the GAP table.



European Efficacy Evaluators

7th European Efficacy Evaluators Meeting in Dublin 2018;

- Adoption of the LWA concept within the renewal authorisation process (Art.43):

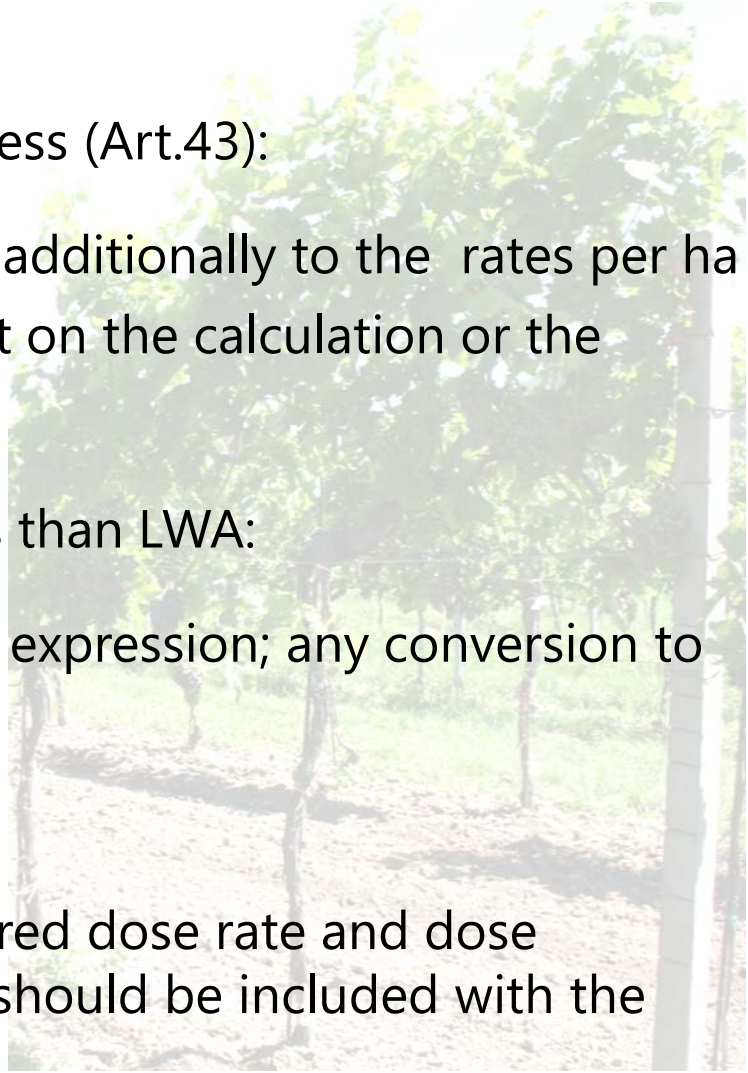
  It is proposed that applicants should state a proper application rate additionally to the rates per ha ground area but without a complete efficacy evaluation; a statement on the calculation or the assumption is needed;

- Handling of reference products registered in other dose expressions than LWA:

  Reference products should be used in the registered dose and dose expression; any conversion to the LWA rate should be avoided;

- Procedure for bridging:

  The old and new formulation should be compared using the registered dose rate and dose expression of the old formulation; In addition, the new formulation should be included with the respective dose rate expression in tLWA;



EPPO Workshop hosted by AGES/ AT

“EPPO Workshop on harmonized dose expression for the zonal evaluation of plant protection products in high growing crops.”

Output of a two days workshop!

Final agreements/conclusions	→	progress on harmonization made
Working groups	→	longterm cooperations initialized
Definition of terms	→	common understanding improved
Revision of PP1/239(2)	→	new insights to be communicated
Impuls	→	further cooperations and agreements initialized (applicants, efficacy evaluators, researchers…)

The Early Belgian Approach

1996:

first attempts to express the dose per ha LWA

→ authorization of new products in top fruits;

2007:

extending the dose expression “dose per ha LWA”

→ glasshouse fruiting vegetables, small fruits and grape vine;

- an appropriate harmonization tool;
- reflects exactly how the treatment is done in practice;
- a complete reporting of the trial parameters is needed;
- implicit assumptions like “standard orchard dimension”, “theoretical spray volume” must be avoided.

Austrian Measures

~ 2014:

First attempts to implement the LWA in the efficacy evaluation:

- in pome fruits and grapevine;
- e.g. by grouping results according to the treated LWA (done by evaluators);
- finally providing additional information such as:

"Efficacy was assessed at an average leaf wall area of 11900 m² (min. 10000 m² – max. 13250 m²)."

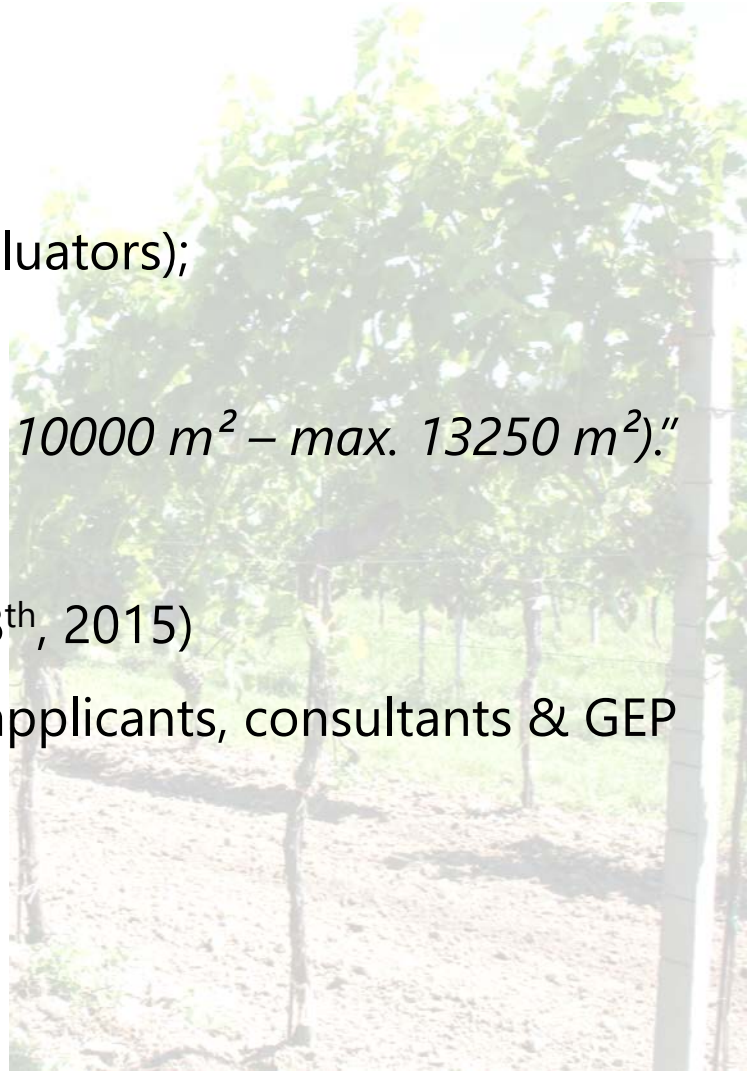
2015:

"Technical discussion on why to use the LWA approach" (October 28th, 2015)

with representatives of the ECPA working group "dose expression", applicants, consultants & GEP certified facilities;

2016:

Hosting the EPPO Workshop



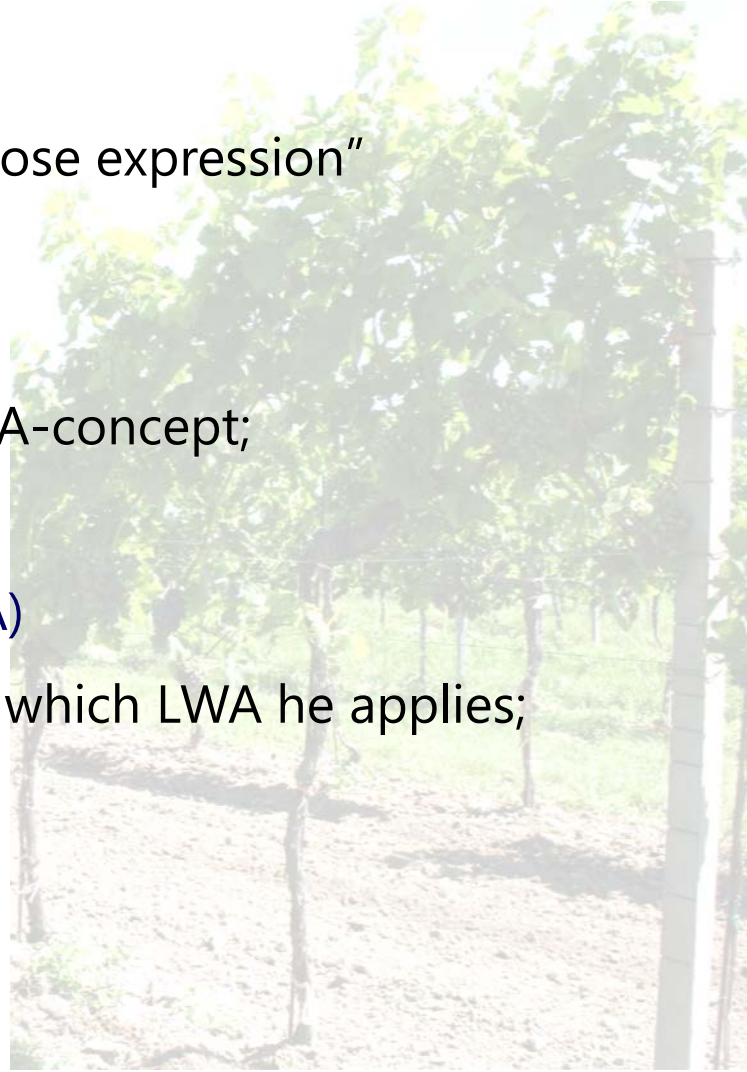
German Efforts

2017:

Meeting and Agreement in February in Braunschweig

German authorities & representatives of the ECPA working group “dose expression”

- Procedure for Orchards, Viticulture, Vegetables;
- New applications with trials planned & carried out based on the LWA-concept;
- Existing approvals will only be accepted remain untouched;
- This procedure can become effective 01.01.2020 (aligned DE + ECPA)
- Renewals need to be recalculated in LWA. The applicant decides for which LWA he applies;



ASSOCIATION OF APPLIED BIOLOGISTS

President: Professor Christine Watson

Association of Applied Biologists
Pesticide Application Group

A two day workshop
at the Universitat Politècnica de Catalunya,
Barcelona, Spain

on 6-7 November 2018