

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

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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

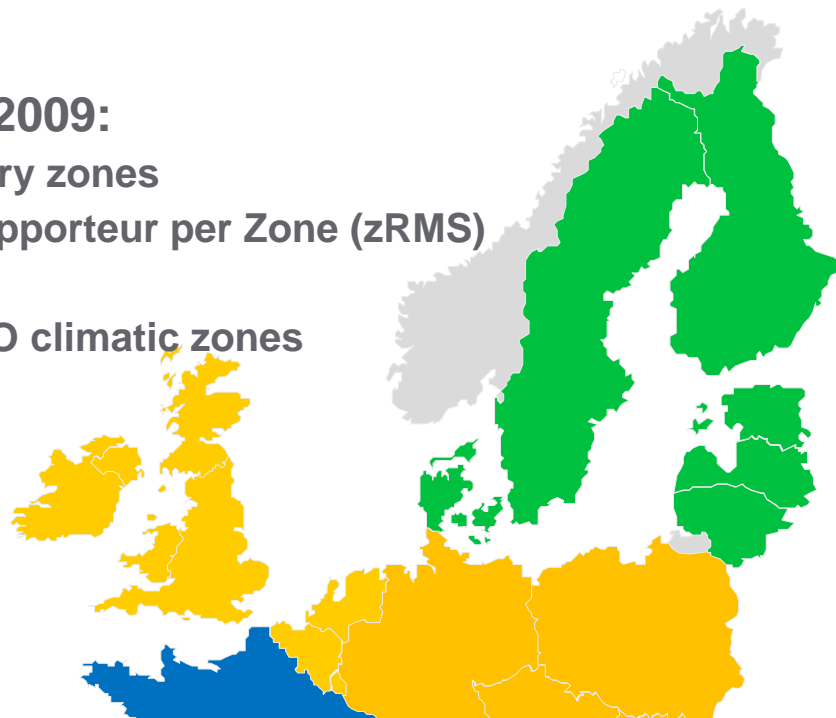
Why is a common dose rate expression so important?

EC 1107/2009:

3 Regulatory zones

1 Zonal Rapporteur per Zone (zRMS)

and 4 EPPO climatic zones



Northern Registration Zone

Central Registration Zone

How can one zRMS evaluate the efficacy for all countries in the zone if the dose expressions are different?



Southern Registration Zone

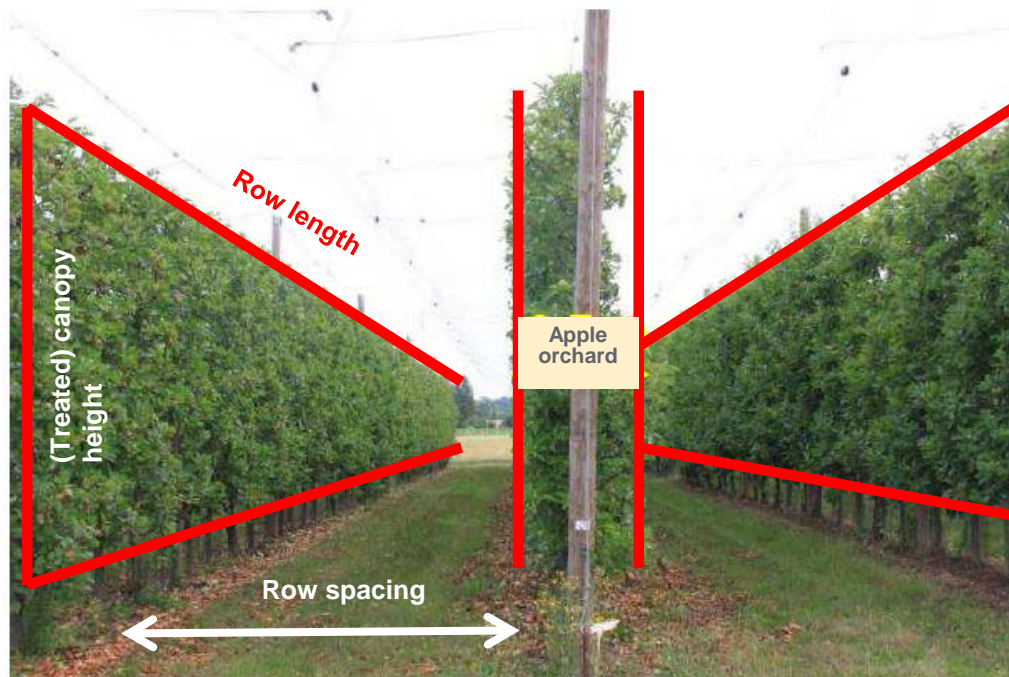
We need a better description than ha ground or hl concentration !



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)

$$\text{Leaf Wall Area (m}^2\text{)} = 2 \times \text{Canopy height (m)} \times \frac{\text{Ground Area (m}^2\text{)}}{\text{Row Spacing (m)}}$$

$$\text{treated Leaf Wall Area (m}^2\text{)} = 2 \times \text{Treated Canopy height (m)} \times \frac{\text{Ground Area (m}^2\text{)}}{\text{Row Spacing (m)}}$$

- 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

 TUNNEL SPRAYERS
www.vitifruitequipment.co.uk/



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

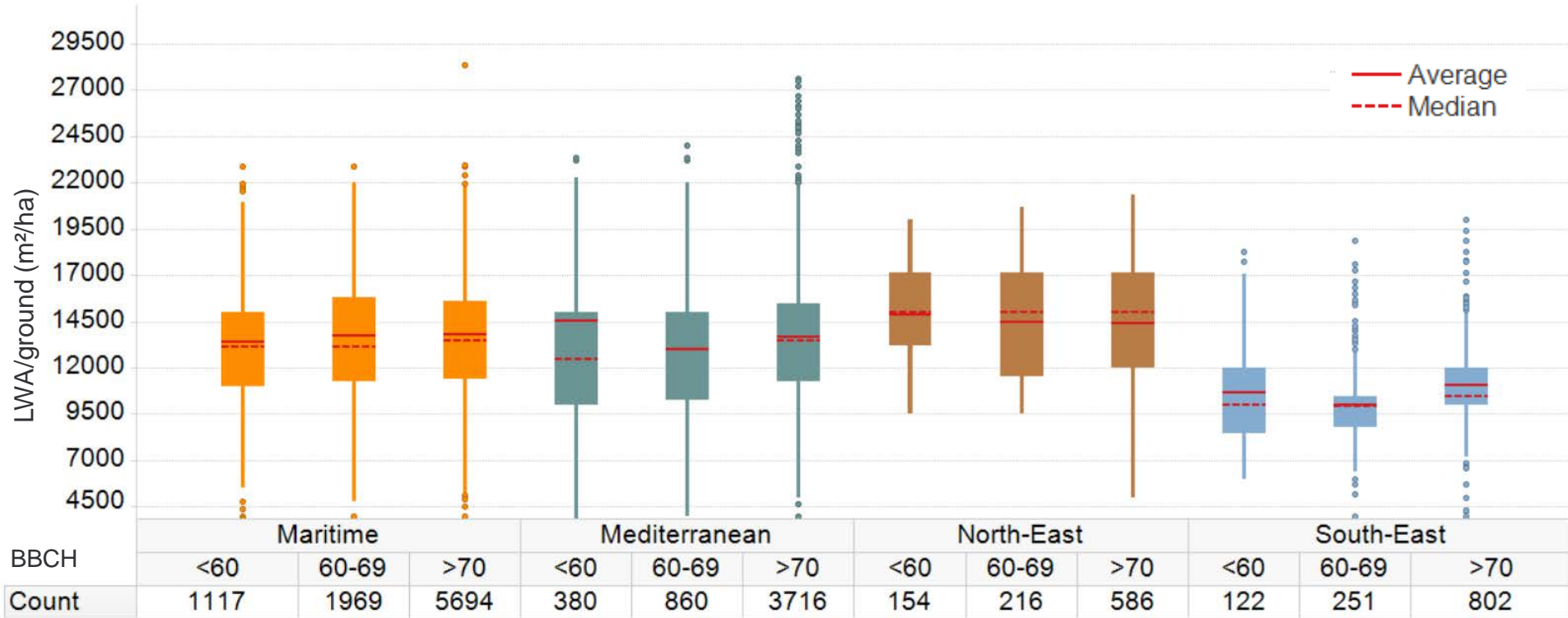
Opportunities

- 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

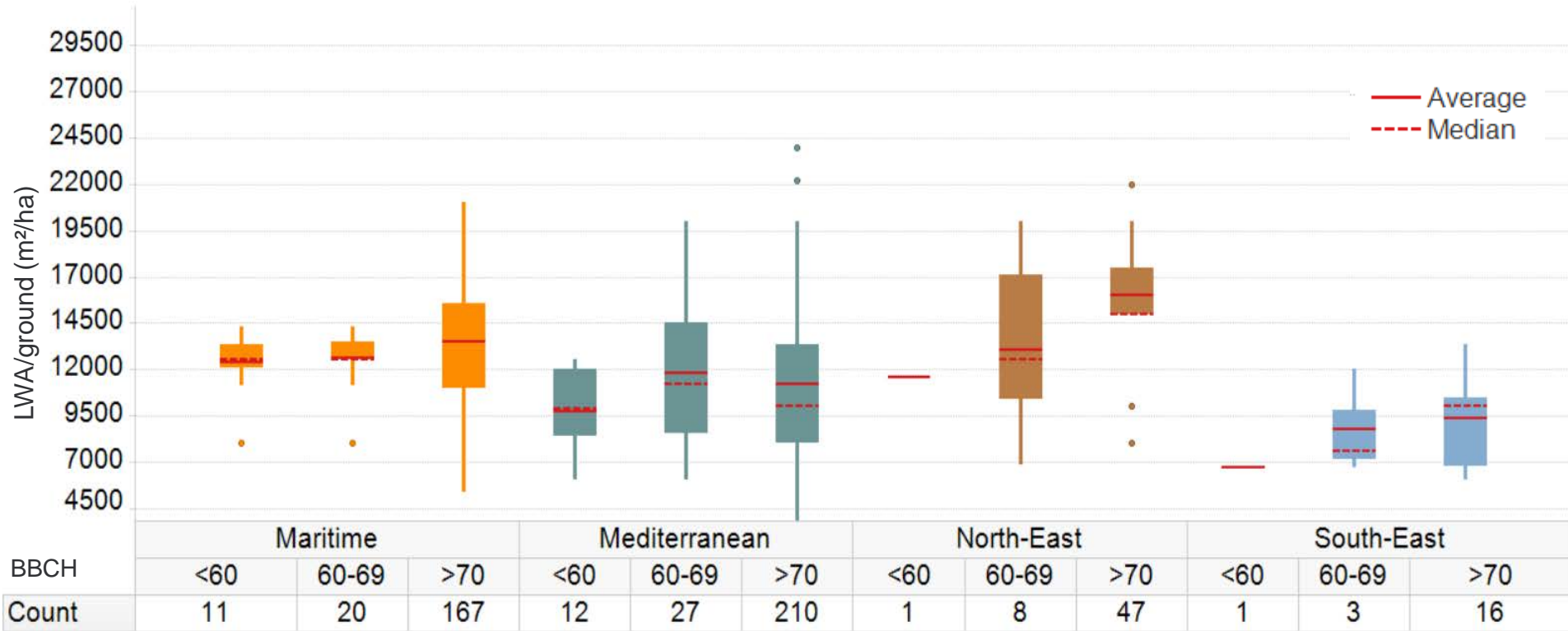
- **Standardization** in measurements and reporting of relevant parameters needed
- Old GEP trial reports may not contain all crop parameter information (treated canopy height) or reported parameters may have been measured incorrect
- Trial sites may differ in their crop parameter from commercial practice

Industry Data - LWA PER EPPO ZONE and BBCH (apple & pear)



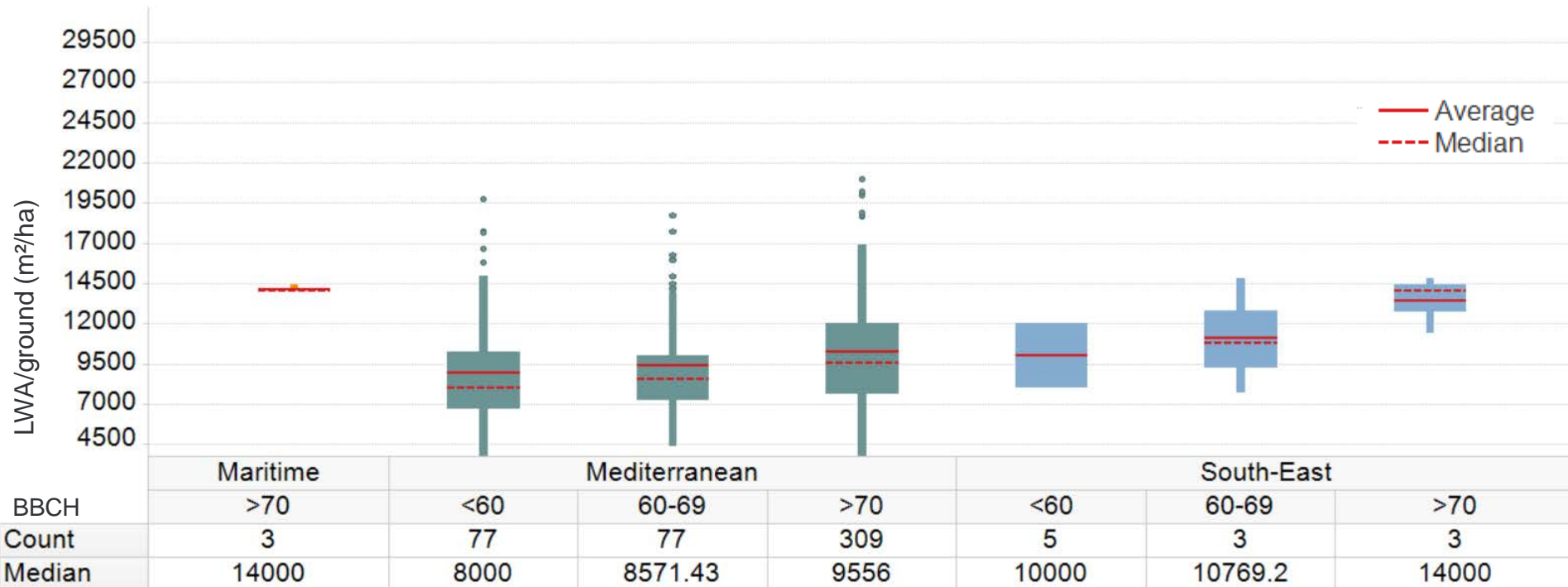
One data point per application, data from 2009 to 2015

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

Median of LWA by Zone, Training / Country / Growth period	00-08 Shooting		09-60 Bud & leaf growth		61-70 Flowering		71-74 Fruit set		75-99 Berries	
	Median	Count	Median	Count	Median	Count	Median	Count	Median	Count
Austria	.	.	5714	23	7333	23	8667	23	9333	27
Czech Republic	.	.	8000	28	8000	27	8276	25	10667	33
Germany	15000	1	10000	228	12657	234	15000	219	15000	337
Hungary	8800	3	6400	30	10000	39	10345	23	10000	45
Slovakia	.	.	7333	18	7333	23	7333	21	7333	22
Slovenia	.	.	4249	7	6080	10	10435	3	8000	10
Switzerland	.	.	7222	47	10500	35	12000	36	12444	89
ALL countries	8800	4	8240	381	11000	391	14000	350	14211	563

One data point per application, data from 2013 to 2015

Industry Data - LWA PER EPPO ZONE and BBCH (grapes) South Reg zone

Median of LWA by Zone, Training / Country / Growth period	00-08 Shooting		09-60 Bud & leaf growth		61-70 Flowering		71-74 Fruit set		75-99 Berries	
	Median	Count	Median	Count	Median	Count	Median	Count	Median	Count
Bulgaria	.	.	7900	4	9100	4	9100	4	9100	4
Croatia	.	.	9750	2	12500	2	14000	1	14000	1
France	12982	4	7200	662	9630	643	10000	486	10706	872
Greece	.	.	12982	28	14042	36	13684	33	15000	47
Italy	667	3	6000	347	7857	321	8571	307	9150	525
Portugal	741	3	5714	111	7208	92	8867	100	9333	133
Romania	.	.	9800	10	10400	13	12000	11	12000	12
Spain	417	3	6762	202	9000	167	9809	168	10000	308
ALL countries	741	13	6667	1366	8889	1278	9512	1110	10000	1902

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

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 countries 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?

