

Status of harmonization of dose expression in 3 D crops for the zonal efficacy evaluation of PPP (Plant Protection Product) in Europe

Suprofruit, Hasselt, 10th May 2017

Schlotter, Peter & Toews, Ralph-Burkhardt on behalf of ECPA (European Crop Protection Association), Sub-team 3 D crops













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Outline

- EU Zonal regulation process 1107/2009
- Why harmonization of dose rate expression?
- (treated) Leaf Wall Area = tLWA
- Recommendations EPPO workshop, Oct. 2016
- Conversion models of dose expression
- Summary















Europe



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4 EPPO Climatic Zones, 3 EU Administration Zones Crop Protection





Why harmonization? Dose rate expressions used in European countries



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	Top fruits	Grapevine	High-growing vegetables	Citrus / Olives
Austria and Germany	Kg/ha/m CH, max. kg/ha	% accord. Eichhorn, max. kg/ha BBCH	Kg/ha/m CH, max. kg/ha	
Belgium	Kg or L /10'000m² LWA, max.kg or l /ha		Kg or L /10'000m ² LWA, max.kg or I /ha	
France	Kg/hl	Kg/ha	Kg/ha	
Greece	%, max. spray vol / ha	%, max. spray vol / ha	%, max. spray vol / ha	%, max. spray vol / ha
Italy	%, min. to max. spray vol / ha	%, max. spray vol / ha	%, max. spray vol / ha	%, max. spray vol / ha
Netherlands	%, max. spray vol / ha		%, max. spray vol / ha	
Norway	Kg/100m row length			
Portugal	%, max. spray vol / ha	%, max. spray vol / ha	%, max. spray vol / ha	%, max. spray vol / ha
Spain	%, max. spray vol / ha	%, max. spray vol / ha	%, max. spray vol / ha	%, max. spray vol / ha
Switzerland	Kg/10'000 m ³ TRV	%, max. spray vol / ha	%, max. spray vol / ha	

6 different dose expression units for top fruits! 3 different expression units in grapevine!

Reference: Tree Fruits Dose Expression Discussion Group Meeting – Wageningen, the Netherlands, September 29, 2009

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





















Pharmaceuticals: dose rate adapted to the body weight





Need for harmonization



- Definition of minimum effective dose
 - cannot be seriously justified
- Efficacy
 - risk of low control values in crops with high LWA
- Phytoxicity
 - risk of phytotoxic effects in crops with low LWA
- Resistance
 - Risk of resistance development in crops with high LWA
- Validity of results for all member states
- Conversion of zonal conclusion to national dose expressions













Agriculture: dose rate adapted to the size of the crop



treated Leaf Wall Area kg or L / 10.000 $\rm m^2$

DAMA

troated $I M A = 2 *$	Spray band height(m) $* 10.000 \text{ m}^2$
treated LWA = 2 *	Spacing between rows (m)

treated LWA = 2 * Spray band height (m) * Row Length (m)







Strength

- **Simple** system easy measured parameters
- Considers seasonal vertical development of the crop and crop parameters
- Already implemented in BE, about to be implemented in AT, support in NL 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 evaluation and registration process
- tLWA rate can be easily converted to national label rate expressions
 trial by trial individually
 - the resulting target rate generally using assumptions















Weakness

- **Simple** system tLWA model may not to be the best model for crop adapted spraying, but it is far better than dose expressions not considering the crop structure
- Not a good fit for **globular** trees
- Additional information reflecting regulatory limitations (dose/ha ground) is needed for the critical GAP and for the farmers' guidance and labels, but not for dose definition trials















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.

















Majority of apple & pear in EU 28: LWA/ha < 17.000 m², median 10.000-15.000 m²













European

Crop Protection

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Industry Data – cherry & plum LWA PER EPPO ZONE and BBCH



One data point per application, 523 data from 2009 to 2016



Majority of cherry & plum in EU 28: LWA/ha < 15.000 m², median 9.500-15.000 m²













Industry Data – grape LWA per EPPO ZONE and BBCH Central Reg.Zone

European **Crop Protection**

One data point per application, data 1.689 from 2013 to 2015

Median of LWA by Zone, Training / Country / Growth	00-08 Shooting		09-60 Bud & leaf growth		61-70 Flowering		71-74 Fruit set		75-99 Berries	
period	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

Grapes in CZ: LWA/ha median 8.000-15.000 m², depends on development stage











Industry Data – grape LWA per EPPO ZONE and BBCH, Southern Reg. Zone Protection

One data point per application, 5.569 data from 2013 to 2015

Median of LWA by Zone, Training / Country / Growth	00-08 Shooting		09-60 Bud & leaf growth		61-70 Flowering		71-74 Fruit set		75-99 Berries	
period	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

Grapes in SZ: LWA/ha median all countries 7.000-15.000 m²,

depends on development stage, differences within countries and regions













Recommendations EPPO workshop, Oct. 2016



- Agreement to use tLWA as dose expression for efficacy trials of PPP for Zonal evaluation in pome fruit, grapevine and high growing vegetables for new registrations
- Kg or L/ha ground is not to be used in the zonal efficacy evaluation as it is not linked to any crop structure. However, the dose/ha ground is to be given in the GAP table
- Expert Working Group (EWG) established
 - on dose conversion
 - on glossary of terms and on measurement of crop parameters
- Citrus and olives (and globular trees) are still under review and evaluators in Europe should discuss any proposal and validate it















Agree on Conversion factors and tLWA/EPPO Zone EPPO workshop, Vienna, Oct. 2016













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Conversion between models of dose expression

When is a conversion factor needed?

- from tLWA rate to critical GAP* rate/ha (used for tox, fate, ecotox risk assessment)
- to convert the proposed target dose rate/tLWA into national expressions on labels
- 3) to keep old trials that did not follow the tLWA approach valid
- GAP = Good agriculture practice: document describing all intended uses













Transfer from Zonal efficacy evaluation to label rates

Simplest approach – if legally accepted:

- Labels display the rate per tLWA (as validated in Zonal efficacy evaluation) plus a max. ha ground rate (as validated in other sections and GAP)
- Plus national expressions (converted from tLWA using agreed parameters)













Summary



- In view of the new zonal evaluation and registration system in the EU, the dose expression harmonisation in efficacy assessments will be a help for zonal rapporteur regulators who need to assess and to register on behalf of several countries
- 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, spray band, 3 D crops)
- Agreement to use tLWA as dose expression for efficacy trials of PPP for Zonal evaluation in pome fruit, grapevine and high growing vegetables for new registrations (EPPO workshop, Oct. 2016). A transition period is needed for all registered PPP
- Other crops (citrus, olives, globular trees) are under evaluation
- Continue harmonization effort in close cooperation is needed













EPPO workshop, Vienna, Oct. 2016



86 participants from 18 EPPO countries, 35 from National Regulatory Authorities, Research Institutes and Universities, 29 from Crop Protection Industry, 20 from Consultants.



http://archives.eppo.int/MEETINGS/2016_conferences/dose_expression.htm















Questions and comments?



















Thank you!

On behalf of ECPA (European Crop Protection Association), sub team 3 D crops

Richard Massie, Adama Martin Teichmann, BASF Ralph Burkhard Toews, Bayer Crop Science Xavier Van Waetermeulen, Bayer Crop Science Jean-Pierre Huby, DuPont Robert Matysiak, DuPont Juan Miguel Cantus, Syngenta Frank Meier-Runge, Syngenta Peter Schlotter, Dow AgroSciences











