



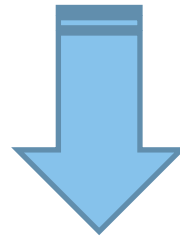
# **EFSA Stakeholders event on non-dietary exposure to plant protection products – March 28<sup>th</sup>, 2022**

CLE OBE TSG – Projects summary

Stephanie Nadzialek

# Introduction

- **EFSA guidance** is seen as a **critical element** for risk evaluation.
- **NEW/relevant data** provide **greater confidence** in decision-making process.



CropLife Europe Operator Bystander Exposure Technical Subgroup (OBE TSG) is highly committed in providing **high quality data** communicated in a **transparent** way.

# Projects identified as relevant for EFSA guidance (1/2):



## Projects fully **completed**:

Project	Topic	Submitted during EFSA data-call	Comment
Re-entry in grapes (BROV)  + new type of PPE/Gloves for workers	Worker	Placeholder	Studies evaluated by CRD and submitted to EFSA. Additional supporting data available for re-entry gloves efficiency (2015 study)
Drift during airblast application (BROV)	Resident/ Bystander	Placeholder	Studies evaluated by CRD and submitted to EFSA.
Drift during groundboom application (BREAM 2&3)	Resident/ Bystander	Yes	BREAM 2 submitted to EFSA. BREAM 3 - Efficacy of drift reduction nozzles proven. All data publicly available.
Dermal absorption to dry residues	Worker	No	Link to online paper: <a href="#">HERE</a>

# Projects identified as relevant for EFSA guidance (2/2):



## Projects ongoing:

Project	Topic	Submitted during EFSA data-call	Comment
Closed transfer system	Operator	No	Public outreach to get regulator input took place end Q1 2021; field part completed.
DFR meta-analysis	Re-entry	No	Data from 180 EU and approx. 200 US DFR trials on vine and orchard crops being extracted. <i>Data evaluation to start Q2/2022.</i>
Adjustment for light clothing for residents and bystanders	Resident/ Bystander	No	<i>Paper submitted to a journal.</i>
Inventory air concentration	Resident/ Bystander	No	<i>Paper (first part) submitted to a journal.</i>
Air concentration of vapour - BROWSE model validation	Resident/ Bystander	No	<i>BROWSE model validation with field measurement data.</i>

# Other OBE TSG projects...

Project	Topic	Project status	Comment
Compounded conservatism in European re-entry worker risk assessment of pesticides	Worker	completed	Link to online paper: <a href="#">HERE</a>
Pesticides in air	Resident	ongoing	<i>Draft report under review.</i>

# In conclusion

## CropLife Europe encourages the Commission and EFSA to provide:

- A clear overview of mid-term and long-term updates and data needs/gaps to this key document.
- A clear and transparent workflow to optimize the inclusion of new and relevant data, e.g.:
  - ✓ GLP/OECD compliant study?
  - ✓ Requirement for close collaboration with EFSA before study initiation? Study call-in from EFSA to all stakeholders?
  - ✓ Procedures for relevant (exposure) information. Are study reports enough?
  - ✓ Common platform for data upload? Collaboration with data owners?

**Clarity and transparency** on coming guidance updates and new data would certainly help to improve efficiency, budget and human resource allocations to support adequate risk assessment.

On behalf of the  
entire OBE TSG,  
thank you for  
your attention!

Member	Company	Email
Edgars Felkers (Chair)	ADAMA	edgars.felkers@adama.com
Sarah Adham	Corteva Agriscience	sarah.adham@corteva.com
Udo Blaschke	BASF	udo.blaschke@basf.com
Kathrin Buerling	Bayer Crop Science	kathrin.buerling@bayer.com
Julien Durand-Reville	Phyteis (France)	jdreville@uipp.net
Emilia Gonzalez	Gowan Crop Protection Ltd	egonzalez@gowanco.com
Christian Kuester	Bayer	christian.kuester@bayer.com
Steven McEuen	FMC	steven.mceuen@fmc.com
Luciano Merolla	Corteva Agriscience	luciano.merolla@corteva.com
Neil Morgan	Syngenta	neil.morgan@syngenta.com
Andre Sarti	Syngenta	Andre.Sarti@syngenta.com
Franz Stauber	BASF	franz.stauber@basf.com
Michel Urtizberea	BASF	michel.urtizberea@basf.com
Anne-Kim Vinck	Bayer Crop Science	kim.vinck@bayer.com
Stephanie Nadzialek	CropLife Europe	stephanie.nadzialek@croplifeeurope.eu



**CropLife**  
EUROPE

# **Update on the BROV project**

Neil Morgan (Syngenta) on behalf of CLE



# Background

- **B**ystander **R**esident **O**rchard **V**ineyard (**BROV**) project
  - Initiated to address perceived data gaps in the EFSA guidance
    - Transfer coefficients relevant to European grape cultivation
    - Newer drift measurements for high crops and more scenarios
  - Working group comprising regulatory bodies and Industry
    - Joint development of reports led by UK HSE
    - Similar approach to AOEM

# Re-entry exposure in vineyards

- Current EFSA default TCs based in US data
  - PDE from Krieger *at al.* (1992) → 30,000 cm<sup>2</sup>/h
  - ADE (no gloves) from ExpoSAC Policy 3 → 10,100 cm<sup>2</sup>/h
- BROV project

Study ID	Location	Activity
1	CZ, DE, FR	Harvest, DFR
2	DE,IT	Pruning
3		DFR
4	DE, FR	Pruning
5		DFR
6	FR	Pruning
7		DFR
8		Pruning, shoot lifting, DFR



Total of 73 workers  
across 3 activities  
Included “partial  
nitrile” gloves

# Re-entry exposure in vineyards

Clothing/PPE	Percentile	Proposed overall TC value (cm <sup>2</sup> /h)
No/light clothing	75 <sup>th</sup> (longer term)	6600
	95 <sup>th</sup> (acute)	9800
No/light clothing and gloves	75 <sup>th</sup> (longer term)	3700
	95 <sup>th</sup> (acute)	6300
Long clothing	75 <sup>th</sup> (longer term)	4500
	95 <sup>th</sup> (acute)	4600
Long clothing and gloves	75 <sup>th</sup> (longer term)	660
	95 <sup>th</sup> (acute)	1100

Significant potential improvement for EU grape re-entry risk assessment with more relevant, robust data  
Not included in the revision to the EFSA guidance  
With raw data for independent review → modular update possible?

# Bystander/resident exposure to spray drift in vineyards and orchards

- Current EFSA approach based on Lloyd *et al.*, 1987
  - *“these data are relatively old and that data for different distances are not available. The WoG recommends that further data are produced to refine the proposed assessment.”*
- BROV drift studies
  - 16 studies → 8 orchard, 8 vineyard
  - Early and late growth stages
  - 4 countries (FR, PO, IT, ES)
  - 2 fungicides
  - Adult and child mannequins
  - PDE, ADE and PIE measured



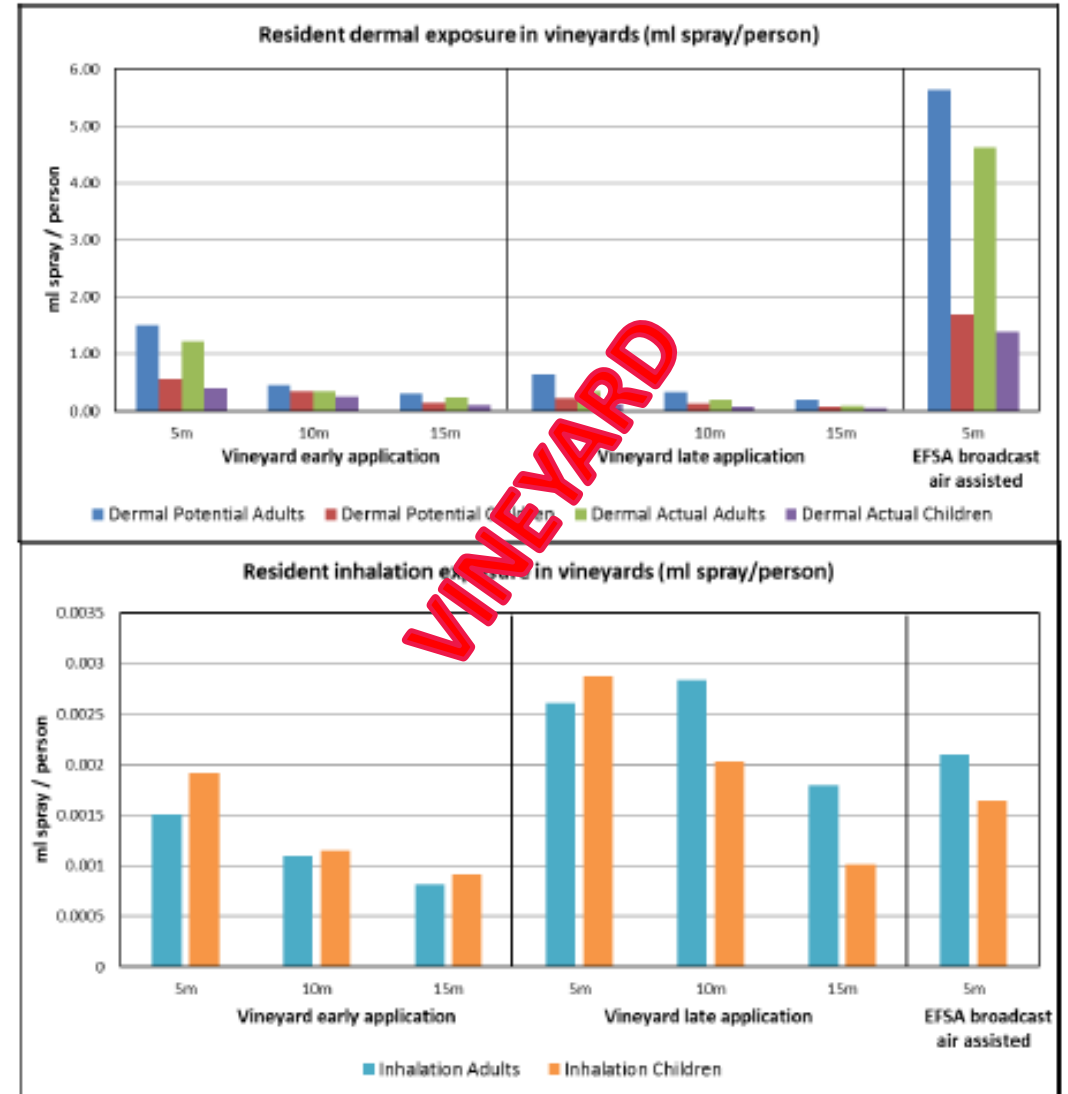
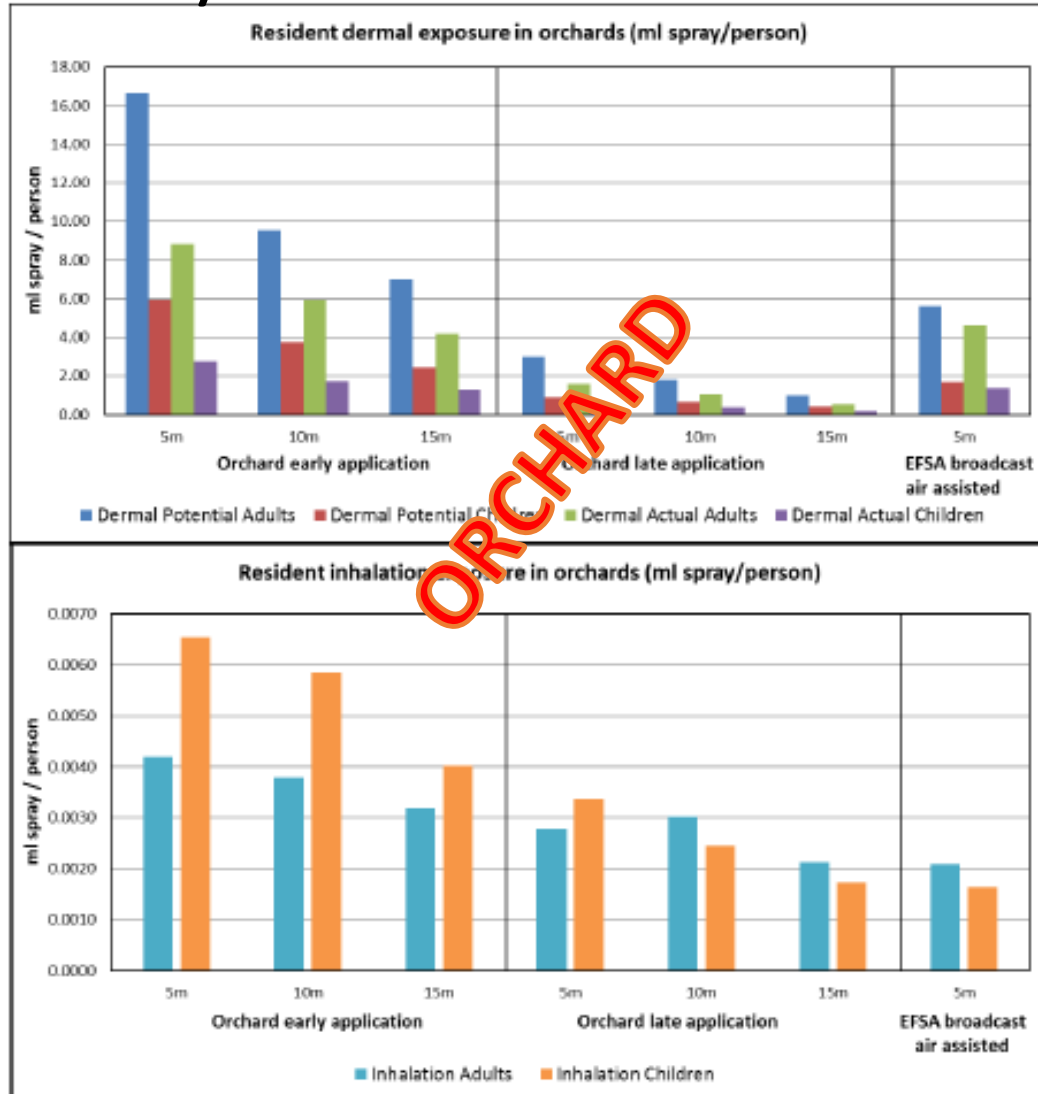
# Bystander/resident exposure to spray drift in vineyards and orchards

Scenario	Growth Stage (BBCH)	HSE proposal for definition of “late season”
Vineyard early	12 to 15	BBCH71 to BBCH93 (fruit size 10mm to leaf fall) (Also suggested Day of Year)
Vineyard late	81	
Orchard early	53 to 57	
Orchard late	81 to 91	

- **Observations**

- Important factors – adult/child, orchard v vineyard, leaf cover, distance
- Exposure lower in vineyards than orchards
- No robust model related to wind speed and direction, sprayer, spray quality and concentration or amount applied

# Bystander/resident exposure to spray drift in vineyards and orchards (HSE graphs)



# Bystander/resident exposure to spray drift in vineyards and orchards

- HSE comments
  - Good range of equipment and real world scenarios
  - Lack of calibration leads to uncertainty in applied volume
    - However this is not significant when comparing ml spray v  $\mu\text{g a.s.}$
  - Observed exposures should be restricted to applications represented by trials – lower rates covered, higher rates *pro rata*
- CLE comments
  - Final report received 09/21, comments returned 12/21
  - Reservations about calculated spray volumes v actual reported values
  - Precautionary approach for values between LOQ and LOD
  - Spiking levels defended
  - Confusion regarding use of exposure percentiles v volume of exposure
- Overall conclusion
  - BROV drift work provides a large database which will improve on the existing EFSA approach