August 2022

CropLife Europe (CLE) Occupational and Bystander Exposure Technical Sub-Group (OBETSG) comments on the BROV drift report[1] prepared by UK HSE

Introduction

As part of the CLE BROV (Bystander Resident Orchard Vineyard) research programme, 16 GLP studies were carried out in orchards and vineyards in four European countries to measure incidental spray drift exposure for bystanders and residents in the vicinity of such crops. This produced a large body of data and CLE invited the UK Health and Safety Executive (HSE) to carry out an independent evaluation of these data and produce a project report. Prior and during the evaluation, additional discussions took place with other independent organisations (BVL, TNO, JKI and SSAU) and with Industry experts and EFSA participated as an observer.

A draft report was made available in September 2021, and this was reviewed by the OBETSG on behalf of the Industry, resulting in a number of comments on the approaches taken and questions of clarification. These comments were returned to HSE in December 2021 with the hope that any agreed changes could be made to produce a final version. However, a long period of inactivity ensued during which several experts who had worked on the report left HSE. So, it was mutually agreed between CLE and HSE that as the relevant resource to act on the comments was no longer available, the report would be published on the CLE website with this document detailing the CLE comments alongside. CLE believe this is a transparent approach to making the relevant information available.

Comments

Section	**Subject matter and comment**
2. Summary (page 4)	"It was concluded that a consistent and practical approach was to consider the variation in exposure with distance from the source."
Comment:	It was not clear to CLE whether this conclusion regarding the influence of downwind distance was reached purely as a result of the statistical analysis of the data, which should be the case.
2. Summary (page 4)	"The vapour monitoring data are not reported in this paper."
Comment:	The data generated by CLE during the BROV drift work included measurements of vapour concentrations in air at two heights to reflect the breathing zones of adult and child bystanders. The majority of measurements were identified as non-detects. The highest measured value was 0.076 µg/m^3 whereas the EFSA guidance would assign a default value of 1 µg/m^3 to both fungicidal active substances based on their vapour pressure, i.e. the EFSA guidance overpredicts exposure to vapour by at least an order of magnitude. CLE would have preferred that

[1] Proposals for new spray drift exposure values in orchard and vineyards for residents and bystanders. Health and Safety Executive (HSE) Hugh Dawick, Paul Hamey, Alan MacDonald, Jenny Chan, Michelle Stevens, Katharine Childs, Jessica Saint-Mart, Catherine Wesley. September 2021.

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	these data were included in the report as they are important in the context of bystander and resident risk assessment.
4. Study design (page 6)	"Sampling began after spray droplets on the dosimeters were deemed to have dried."
Comment:	As it is important to be clear that this relates to vapour sampling only, CLE would have preferred the phrase "Sampling ***of vapour*** began after spray droplets on the dosimeters were deemed to have dried."
4. Study design - Field recoveries (page 7)	For cotton dosimeters actual measured values ranged from LOD to 3000 µg/sample and were well outside the range tested. Ideally a third spiking level (e.g. 1000 µg/sample) would be necessary.
Comment:	This statement does not appear to reflect the fact that spiking was conducted on a matrix surface of area 300 cm^2. To compare the measured analytical results for dosimeter sections, the upper spiking level of 100 µg/300 cm^2 needs to be extrapolated to the respective dosimeter section surface area, and the resulting spiking level can then be compared to the corresponding analytical dosimeter result. CLE performed this calculation, showing that most results are covered by the high spiking level, or at least that the high spiking level is in the range of the 99%ile of the dosimeter result distribution with few exceptions (one high level range for the adults (inner dosimeter for lower legs) and one for child (head/neck). CLE would state confidently, therefore, that the high level spiking range does actually cover the residue range detected in the different dosimeters and is not “well outside the range tested”.
4. Study design - LOD/LOQ (page 7)	"Therefore, in this case a slightly different approach was taken: measured values between LOQ and LOD were substituted with the LOQ and values reported as ND were substituted with the LOD relevant to each active."
Comment:	CLE believes this to be a precautionary approach and would have suggested using values midway between the LOQ and LOD for each active substance when the measured residue fell within this range.
4. Study design - Wind direction (page 8)	"The direction of angle...negative value."
Comment:	This section of the report on correcting the wind directions was considered quite difficult to follow and would have benefitted from clarification. Clearly a great deal of effort has gone into this exercise, but it is not immediately obvious how such corrections influenced the outcome of the evaluation of the data.

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4. Study design - Spray volume and amount of active substance applied (page 15, Fig. 9)	Study ID ECPA_8 (CEMR-7457) Suggested difference according to CRD/Silsoe report is " -629% " Study ID ECPA_15 (CEMR-8026) Suggested difference according to CRD/Silsoe report is " -413% "
Comment:	CLE expressed reservations about the Silsoe Spray Applications Unit (SSAU) estimations of applied volume as exemplified in the following 2 cases. In the first, according to SSAU, the application rate was 1093 L/ha, whereas the contract research organisation (CEMAS) reported it to be 150 L/ha. The area treated area was 1.2 ha, which would extrapolate to a total applied volume of 1311 L if SSAU's estimation is correct. However, this represents greater than two full tanks as the sprayer, a Dragone Athos 500 has a 500 L tank. It was not reported that the sprayer was refilled which would likely have been the case if it was necessary. Similarly, in the second case, whereas CEMAS reported a volume rate of 140 L/ha, the SSAU report suggests that this should have been 718 L/ha. The Calvet sprayer had a tank capacity of 800 L and so the total volume of 1142 L estimated for the 1.59 ha plot would have meant refilling the tank. Again, this was not reported. The CRO is well respected and very experienced and CLE wonder whether such mistakes are likely to have been made and whether estimating applied volume from proprietary nozzle flow rate values is more reliable.
4. Study design (pages 11 and 13)	Interpretation of BBCH stages.
Comment:	The report makes the following assertions regarding the distinction between early and late growth stages for orchards and vineyards: "Assuming a roughly similar relationship for orchards in other EU countries in which the BROV trials were undertaken, early stage applications appear to occur between DOY 60-100 and late stage applications between DOY 240-270." "For risk assessment purposes it is proposed that late (dense foliage) application can be assumed in orchards for which the BBCH growth stage is from 71 to 93 (beginning of leaf fall). For vineyards the later development stages are equivalent to orchards such that BBCH 71 also equates to the beginning of fruit development and BBCH 93 to the beginning of leaf fall so the same criteria could apply."

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	For reference: - DOY 60-100 = Mar 01 – Apr 10 - DOY 240-270 = Aug 28 – Sep 27 The distinction between early and late stage in the EFSA guidance on non-dietary exposure has lacked transparency since its first publication in 2014 and CLE welcomes any attempt to address this as it has a significant impact on estimated exposure to spray drift. However, it should be recognised that although the applications of the 2 fungicide formulations used in the BROV research fell within fairly well defined intervals, there will be many cases where this simplistic definition may be less relevant. For example, if the label presented a range of BBCH stages which spanned the proposed intervals, say BBCH 51-81, 2 assessments might be necessary to cover the relevant scenarios. Also, if for example BBCH 81 fell in July, there remains the question as to whether BBCH stage or DOY should be taken into account to determine the applicability of the BROV data. According to the EFSA guidance, the late stage, dense crop scenario for orchard crops is associated with higher exposures for spray operators and lower exposures for bystanders and residents. Defining these scenarios according to DOY rather than BBCH could help to ensure that risk assessment does not result in worst case exposures for operators and residents/bystanders at the same time.
7. Conclusions (page 19)	Dependence of results on application rate.
Comment:	It is stated in the report that "the observed percentiles should be regarded as representative exposure values for applications involving similar application rates to those in the trials" and that *pro rata* extrapolation should be used for higher rates. It is not clear how this would be implemented as the use of a volume of exposure (mL/person) has been accepted as a reasonable metric in other parts of the report and taking into consideration the relevant highest concentration would already extrapolate the data to higher rates. Consequently, CLE believes that the mL/person approach does not need any further extrapolation.
Appendix D, Appendix F (pages 45 and 101)	Percentiles.

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Comment:	According to the EFSA guidance, spray drift exposure calculations for residents use 75th percentiles for the volume of contamination, with the 95th percentiles being taken for bystanders (acute scenario). Both of these statistics are reported in Appendix F (p101). However, for the resident, arithmetic mean values are also needed to calculate summed exposures for all pathways. As the means are not reported and the derivation of the statistics is not transparent, it will be difficult to complete a risk assessment for the resident using the data provided.

Conclusions

CLE thanks the UK HSE for providing a report which for the most part provides a robust independent evaluation of the study data provided but would like these comments to be read alongside the report to ensure our scientific opinion is considered. When the data are submitted for further independent evaluation by EFSA, CLE invites the working group to give this opinion due consideration.