Summary and template

Proposals for new transfer coefficient (TC) values for worker re-entry activities in vineyards

Bystander Resident Orchard Vineyard (BROV) Re-entry Project Report
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Abstract
New transfer coefficient (TC) values have been proposed for vineyard workers handling treated grapevines when carrying out harvesting and crop maintenance activities. The evaluation was performed by a joint working group (ECPA BROV [Bystander Resident Orchard Vineyard] re-entry project) chaired by the UK Health and Safety Executive (HSE) in cooperation with the German Federal Office of Consumer Protection and Food Safety (BVL); TNO Netherlands; the German Federal Research Centre for Cultivated Plants, Julius Kühn Institut (JKI), the UK Silsoe Spray Applications Unit (SSAU), the European Crop Protection Association (ECPA) and as an observer the European Food Safety Authority (EFSA). The data base underlying the proposed new TC values is originating from re-entry exposure studies in combination with concurrent dislodgeable foliar residue (DFR) studies, which were all performed by industry to support product authorizations and on behalf of industry associations (ECPA and UIPP). The objective has been to specifically investigate TC values that reflect European working practices in vines.

TC values for various re-entry activities have been derived from five pairs of concurrent re-entry worker exposure studies and DFR studies performed in the Czech Republic, Germany, France and Italy between 2004 and 2017. The studies were performed in wine grapes and cover the following activities: hand harvesting, pruning/training, and training/shoot lifting in vineyards. The test materials were all fungicides (iprovalicarb, dimethomorph, dithianon, pyrimethanil and fenbuconazole) with foliar treatments following the recommended application rates and timing of the products. A total of 73 workers at 16 sites were monitored for a full working day. The methodology applied was whole body dosimetry comprising inner and outer dosimeters in combination with face wipes and hand washes. In one study partial nitrile gloves were used. (20 workers). In the concurrent DFR studies leaf punches were taken at each site to correspond with the time of worker re-entry.
Potential exposure values (for both the body and the hands) showed a good correlation with the DFR values. Total (body and hands) TC values based on the BROV studies are lower than the current default values in the EFSA Guidance Document (Reference 1) for both potential worker exposure and assuming the use of workwear with bare hands.

The Transfer Coefficient values proposed by the BROV working group are as follows.

Proposed Transfer Coefficients (cm^2/h)		
Clothing and PPE	**Percentile estimate**	**Total TC**
No clothing or light clothing, no gloves	75^{th} percentile	6600
	95^{th} percentile	9800
No clothing or light clothing, work gloves*	75^{th} percentile	3700
	95^{th} percentile	6300
Full length clothing**, no gloves	75^{th} percentile	3500
	95^{th} percentile	4600
Full length clothing**, work gloves*	75^{th} percentile	660
	95^{th} percentile	1100

*partial nitrile gloves (10% penetration assumed); **single layer of long sleeved and long-legged clothing

Introduction

In the EFSA guidance document [EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874] two preliminary TC values have been suggested to support harmonized risk assessment approaches for worker re-entry activities in vineyards: the TC value of 30,000 cm²/h for total potential exposure and 10,100 cm²/h for actual dermal exposure assuming that arms, body and legs are covered by long sleeved and long legged work wear and bare hands. The current TC value for total potential exposure (30,000 cm²/h) has been derived from the maximum value of a set of US data generated in tree fruit and has been considered precautionary for the re-entry scenario in vineyards. The current EFSA-recommended TC value for actual dermal exposure (10,100 cm²/h) is based on the values summarized in the US EPA Science Advisory Council for Exposure Policy [The US EPA Office of Pesticide Programmes Science Advisory Council for Exposure (ExpoSAC) Policy 3)]. The values are based on unpublished US Agricultural Re-entry Task Force data with no detailed information available to EFSA. In the ExpoSAC document the TC of 10,100 cm²/h for actual dermal exposure is described as being applicable to tying/training, hand harvesting and leaf pulling tasks in grapes. Due to the lack of underlying information for detailed scientific scrutiny of the values the following recommendation was given by EFSA: "*The [EFSA] WoG strongly recommends further collection/production of data on specific TC and DFR values to produce more realistic exposure assessments*". The objective of the ECPA BROV re-entry project has been to establish EU TC values for relevant re-entry activities in vineyards. European field studies have therefore been collected from ECPA member companies and additional studies were conducted on behalf of ECPA and UIPP to establish an extended generic data base. All study information has been made available to the BROV joint working group for the detailed scientific review and proposal of TC values.

Materials and methods

Study sites and worker tasks

The BROV re-entry database includes five matched pairs of worker re-entry exposure and DFR studies presented in a total of eight study reports. In two of these studies (study pairs 2 & 3 and 4 & 5), field plots of DFR sampling was separate and in vicinity of the locations where worker exposure monitoring was performed but belonged to the same set-up of study. Worker activities in the vineyards comprised hand harvesting, pruning, training and shoot lifting. The locations of the field sites were in the Czech Republic, Germany, France and Italy. At each of the 16 field sites 4 to 6 experienced workers were monitored for a full working day (a total of 73 workers involved). The details of the worker exposure and DFR studies are summarized in Table 1 below.

Table 1: Overview of studies investigated

Study ID	No. of field sites	Activity monitored	Year of field work	Country of study	No. of subjects monitored
1	6 (3 used)	Hand harvest & DFR	2015-2016	CZ, DE, FR	17
2	3	Pruning	2016	DE, IT	12
3		DFR			-
4	3	Pruning	2016	DE, FR	12
5		DFR			-
6	3	Pruning & training	2004	FR	12
7		DFR			-
8	4	Pruning, shoot lifting & DFR	2017	FR, IT	20

Test materials

The test materials were all fungicides approved for use in grapevines and were formulated as water-dispersible granules (WG, 3 study pairs), a suspension concentrate (SC, 1 study pair) or an oil-in-water emulsion (EW, 1 study pair). The products contained in total 6 different active substances, 5 of which were analyzed in the studies.

Table 2: Overview of test materials applied

BROV study ID	Product	Active substance	Formulation type
1	Melodi Combi (Sirbel UD)	Iprovaliarb, 90 g/kg (+ Folpet, not analyzed)	WG
2	BAS 553 01 F	Dimethomorph, 150 g/kg Dithianon, 350 g/kg	WG
3			
4	BAS 605 04 F	Pyrimethanil, 411.7 g/L	SC
5			
6	Indar EW	Fenbuconazole, 50 g/L	EW
7			
8	Melodi Combi (Sirbel UD)	Iprovaliarb, 90 g/kg (+ Folpet, not analyzed)	WG

Exposure study methodology

The methodology used in the exposure monitoring studies was based on the recommendations of the OECD Guidance Document (97)148 [OECD (Organisation for Economic Co-operation and Development), 1997. Guidance document for the conduct of studies of occupational exposure to pesticides during agricultural application. Series on testing and assessment No. 9. GD (97) 148]. The study subjects at each site were experienced workers or less experienced seasonal/casual workers under supervision. The duration of the exposure monitoring (between 4 hours and 7 hours 45 minutes) reflected the actual duration of the task being performed or a full working day. The exposure studies considered the dermal route only (additional air monitoring in some of the studies has been disregarded for the purposes of this project) using the range of dosimeters summarized below.

Outer body dosimeters consisted of polyester cotton blend materials (65%:35%), either as work jackets (BROV study ID 1 and 8) or as whole-body dosimeters (combination of long-sleeved shirt and long trousers, or coverall). **Inner body dosimeters** consisted of long-sleeved T-shirt and long johns (100% cotton). On some occasions (BROV Study ID 1, sites 1 and 2, BROV Study ID 8) workers chose to wear an additional shirt between the outer and inner dosimeters. In this case, the analytical findings of the additional shirt were attributed to the inner body dosimeter (referred as actual dermal exposure as aggregate values of inner and intermediate dosimeters). In some studies, **partial nitrile gloves** were worn (BROV Study ID 2, site 1 and BROV Study ID 8, but only sampled here). Partial nitrile gloves consisted of protective nitrile coating on palms of hands and fingers, with uncoated fabric on the back of gloves to allow breathability. In most studies, worker performed re-entry operations with **bare hands** and actual hand exposure was monitored by means of the hand wash methodology with two sequential hand washes using aqueous detergent hand wash solutions. **Face/neck** exposure was monitored by two sequential wipes with multi-layer cotton gauze pads moistened with aqueous detergent solution. One worker (BROV Study ID 2) used a dust mask in addition but the analytical findings in this sampling medium were not used because it was not considered a reliable dosimeter for predicting dermal exposure to the face.

DFR study methodology

The methodology used in the DFR studies followed the recommendations of the US EPA Guidance Series 875 [The US EPA Office of Pesticide Programmes Series 875 Occupational and Residential Exposure Test Guidelines. Group B – Post-application Exposure Monitoring Test Guidelines. Part B, Chapter 3: Dislodgeable Foliar Residue Dissipation: Agricultural Guideline 875.2100. Part C: Quality assurance/Quality Control (QA/QC)]. In most studies DFR samples were taken at the same time and in the same location as the associated re-entry activity. For some studies (study pairs 2 & 3 and 4 & 5) DFR sampling was performed in vicinity of the locations where worker exposure was monitored. Application rates and application timing were identical to the concomitant re-entry studies. DFR values concurrent with the re-entry operations were used although some of the studies included additional sampling events which were disregarded for the calculation of the TC value. The sampling method involved taking leaf punch samples from foliage within the worker contact zone. The punched area of each leaf disc (expressed as the 2-sided leaf surface area) was 5 cm^2 (study 1) or 10 cm^2 (all other studies). Each sample represented a 2-sided area of 400 cm^2 in total, equivalent to 80 leaf discs (study 1) or 40 leaf discs (all other studies) and 3 replicate sets of samples (5 replicates for study 1) were taken at each sampling event. Foliar residues were dislodged from leaf discs using an aqueous solution (0.01%) of Aerosol OT-100 with an extraction volume of 200 ml per sample.

Quality assurance, handling of (field, travel) recovery samples and method validation
The field and laboratory phases of all studies were GLP compliant (apart from some of the weather monitoring data) and complied with OECD (97)148 for exposure measurements (Reference. 2), EPA Series 875 (Reference 3) for DFR measurements and SANCO 3029/99 (Reference 4) for residues methods of analysis. Analytical results of exposure monitoring samples were corrected for incomplete recovery only if the field recovery for the matrix was <95% for the relevant fortification level at the respective site. Either 2 or 3 field fortification levels and an untreated control (UTC) for each matrix were applied at each site, with 3 replicates at all sites apart from study 8 (the latter having 1 replicate analyzed out of the 3 replicates prepared for each spiking level and the UTC for each matrix at each site, thus, mean recoveries for each matrix and spiking level were calculated across all sites). The BROV WoG was consent that the lack of replication for the field recovery samples in study 8 was not a concern for the reliability of the monitoring results. Field recovery samples (other than hand-wash solutions) were exposed to environmental conditions, in an area free from contamination, for the duration of the exposure monitoring period. Inner dosimeter samples were covered by a layer of unfortified outer dosimeter material to comply with environmental conditions. Travel recovery samples (optional according to guidance) were generated in some of the exposure studies but not always for all sites, matrices or spiking levels. They were packed and frozen immediately after fortification without prior exposure to environmental conditions, shipped and stored with the field recovery and field monitoring samples.

Application and site details
Application of re-entry sites were performed by means of typical commercial equipment (tractor mounted or trailed air assisted sprayers, trailed axial, crossflow, ducted broadcast air assisted and vertical boom recirculating (tunnel) sprayers and air assisted directed sprayers) at areas of about 0.8 to 5.0 ha. Re-entry worker exposure sites and DFR sampling sites were at the identical location for BROV studies 1, 6, 7 and 8. In two studies re-entry exposure sites and DFR sampling sites were kept separate (BROV study pairs 2 & 3 and 4 & 5. In these separate DFR sampling sites applications were performed by means of hand-held equipment (knapsack mist blowers) at areas of about 0.01 to 0.03 ha. Where the same site was used for re-entry exposure and DFR sampling, a separate plot was allocated for the DFR sampling. The difference in the type of application equipment chosen (re-entry plot versus DFR plot in study pairs 2 & 3 and 4 & 5) was not considered to be of concern but a separate analysis of TC calculations was performed with and without these mismatched studies.
Applications were in general performed at the maximum authorized application rate and maximum number of treatments. In some cases, reduced application rates were applied following normal commercial practice to adjust to the crop and disease development. Applications were performed at full foliage. In study 1 re-entry exposure monitoring and DFR sampling was performed on days 41 or 31 after the terminal application at harvest. For the other studies these activities were between day 0 and 2 after the terminal application.
The summary of dates of application, re-entry of sites by workers and DFR sampling is presented in the Table 3 below.

Table 3: Dates of application, re-entry and DFR sampling

BROV study	Site	Application date (Growth stage GS, BBCH)				Re-entry date (GS)	DFR sampling date
1	1	01/06/15	11/06/15	22/06/15	05/08/15	41 DAA*4 (GS 89)	41 DAA4 (GS 89)
	2	27/07/15	04/08/15	17/08/15	27/08/15	31 DAA4 (GS 89)	31 DAA4 (GS 89)
	3	08/07/16	19/07/16	28/07/16	29/08/16	31 DAA4 (GS 89)	31 DAA4 (GS
2	1	09/05/16 (GS 55)	20/05/16 (GS 57)	10/06/16 (GS 71)	-	0 DAA3 (GS 71)	
	2[1]	06/06/16	15/06/16	27/06/16 (GS 71)	-	1 DAA3 (GS 73)	
	3	09/06/16	19/06/16	29/06/16 (GS 75)	-	1 DAA3 (GS 75)	
3	1	09/05/16 (GS 55)	20/05/16 (GS 57)	10/06/16 (GS 71)	-		0 DAA3 (GS 71)
	2[1]	07/06/16 (GS 55)	18/06/16 (GS 63)	28/06/16 (GS 71)	-		0 DAA3 (GS 71)
	3	09/06/16 (GS 55-58)	19/06/16 (GS 61-65)	29/06/16 (GS 69-71)	-		1 DAA 3 (GS 69-71)
4[2]	1	25/07/16 (GS 79)	-	-	-	1 DAA1 (GS 79)	
	2	19/07/16 (GS 79)/	-	-	-	1 DAA1 (GS 79)	
	3	18/07/16 (GS79)	-	-	-	1 DAA1 (GS 79)	
5[2]	1	26/07/16 (GS 79)	-	-	-		1 DAA1 (GS 79)
	2	21/07/16 (GS 79)/	-	-	-		1 DAA1 (GS 79)
	3	20/07/16 (GS75-77)	-	-	-		1 DAA1 (GS 75-77)
6	1	23/06/04 (GS 72-73)	-	-	-	2 DAA1 (GS72-73)	
	2	29/06/04 (GS 75)	-	-	-	1 DAA1 (GS 75)	
	3	01/07/04 (GS 73)	-	-	-	1 DAA1 (GS 73)	
7	1	23/06/04 (GS 72-73)	07/07/04	21/07/04	-		2 DAA1 (GS72-73)
	2	29/06/04 (GS 75)	16/07/04	30/07/04	-		1 DAA1 (GS 75)
	3	01/07/04 (GS 73)	15/07/04	29/07/04	-		1 DAA1 (GS 73)
8	1	23/05/17 (GS 61)	–	-	-	2 DAA1 (GS 61)	2 DAA1 (GS 61)
	2	12/06/17 (GS 65)	-	-	-	2 DAA1 (GS 65)	2 DAA1 (GS 65)
	3	20/06/17 (GS 63-75)	-	-	-	2 DAA1 (GS 63-71)	2 DAA1 (GS 63-71)
	4	18/06/17 (GS 75)	-	-	-	2 DAA1 (GS 75)	2 DAA1 (GS 75)

* DAA Day After Application

[1] Study 2 (exposure) and study 3 (DFR) were performed at different sites. The application dates at site 2 in these studies were not identical and, although the re-entry event was on the same day as DFR sampling, the re-entry date was 1 day after application 3 whereas the DFR sampling date was 0 days after application 3. Considering the indicative DT50s of the active substances in these studies (7 days and 20 days) this mismatch is not considered to be a major problem.

[2] Study 4 (exposure) and study 5 (DFR) were performed at different sites. The application dates at all sites in these studies were not identical. However, for all sites the re-entry event and the DFR sampling date were the same time after treatment (1 day after the single application in all cases).

[3] Study 6 (exposure) and study 7 (DFR) were performed at the same sites. Although the DFR study reported 3 applications (with a range of appropriate sample timings), the worker re-entry event was either 1 or 2 days after application 1. So, for the purposes of calculating a TC, only the first application has been considered.

For paired studies 2 & 3 and 4 & 5 there were also differences in grape variety, application rates and spray volumes as summarized below:

Table 4: Differences in paired studies 2 & 3 and 4 &5 (re-entry exposure and DFR studies)

Study parameter	Site	Paired studies 2 and 3		Paired studies 4 and 5	
		Study 2 Exposure	**Study 3 DFR**	**Study 4 Exposure**	**Study 5 DFR**
Location	1	Sandra, Veneto, IT		St. Martial, Aquitaine, FR [1]	St Pardon de Conques, Aquitaine, FR [1]
	2	Merdingen, Baden-Württemberg, DE		Merdingen, Baden-Württemberg, DE [2]	Breisach am Rhein, Baden-Württemberg, DE [2]
	3	Heuchelheim, Rheinland-Pfalz, DE [3]	Partenheim, Rheinland-Pfalz, DE [3]	Heuchelheim, Rheinland-Pfalz, DE [4]	Partenheim, Rheinland-Pfalz, DE [4]
Grape variety	1	Corvina		Merlot, Cabernet Franc	Merlot
	2	Blauer Spätburgunder	Müller Thurgau	Blauer Spätburgunder	
	3	Spätburgunder Merlot	Weisser Burgunder	Dornfelder, Riesling, Merlot, Pinot Noir	Weisser Burgunder
Dose product T1 (l or kg/ha)	1	1.50	1.39	2.50	2.49
	2	1.50	1.599	2.00	2.08
	3	0.96	1.395	2.00	1.95
Dose product T2 (l or kg/ha)	1	1.50	1.483	Not applicable	
	2	1.50	1.691		
	3	1.20	1.519		
Dose product T3 (l or kg/ha)	1	1.50	1.367		
	2	1.50	1.425		
	3	1.44	1.481		
Total dose product (l or kg/ha)	1	4.50	4.24	2.50	2.49
	2	4.50	4.715	2.00	2.08
	3	3.60	4.395	2.00	1.96
Spray volume T1 (l/ha)	1	300	371	200	249
	2	350	320	250	208
	3	300	372	300	293
Spray volume T2 (l/ha)	1	300	396	Not applicable	
	2	450	338		
	3	400	405		
Spray volume T3 (l/ha)	1	300	364		
	2	550	285		
	3	400	395		

[1] Distance between the sites of the exposure and DFR parts of the study is estimated to be approximately 10 km using on-line map search information
[2] Distance between the sites of the exposure and DFR parts of the study is estimated to be approximately 8 km using on-line map search information
[3, 4] Distance between the sites of the exposure and DFR parts of the study is estimated to be approximately 45 km using on-line map search information

Besides differences in locations and crop varieties as shown in Table 4 there were some differences in application rates affecting paired study 2 & 3 and sampling dates affecting paired study 4 & 5. Although the application dates in study 4 (exposure) and study 5 (DFR) were not identical, for all sites in these studies the re-entry event and the DFR sampling date were the same time after treatment (1 day after the single application in all cases). So, even though the analyte in these studies had an indicative DT50 <2 days, the mismatch in the application dates (by between 1 and 2 days) is not considered to be of importance. For study pair 2 & 3 there was minor difference of one day between re-entry and DFR sampling (see Table 3) and there were minor differences in application rates with higher rates in the corresponding DFR parts notably at application dates T1 and T2. Since the foliar residues at the time of re-entry and DFR sampling mainly resulted from the terminal application and terminal application rates matched in both, the exposure part and the DFR part, the WoG concluded that the information from study pairs 2 & 3 and 4 & 5 was adequate for the purpose of setting the TC for re-entry operations in grapes.

Sample handling

The outer and inner whole-body dosimeters (mainly 65% polyester, 35% cotton, or 100% cotton) were cut into arms, legs and torso. In BROV study 6, arms and legs were further sectioned into upper and lower parts. All re-entry workers except those of BROV study 8 were performing re-entry operations with bare hands. Hand washes were usually performed with 1000 ml aqueous Aerosol OT-100 (0.01%) solution. In BROV study 8 gloves were worn (polyamide knitted gloves with palm and fingers coated with nitrile) Single hand washes each with 1000 ml aqueous 0.4% Esemtan solution were applied in this study. Face/neck wipes (two sequential ones) were performed with multi-layer cotton gauze pads moistened with 4 ml aqueous Aerosol AT-100 solution (0.01%) or 0.4% Esemtan solution (BROV study 8). DFR sample generation was done on subplots separate from the re-entry plots. In general, three subplots per study site were sampled. Leaf punchers were used to produce 40 leaf discs of each 10 cm^2 (two sided). In BROV study 1, 80 leaf discs of each 5 cm^2 were produced. In all studies dislodging of foliar residues was done by means of two washing procedures with aqueous Aerosol OT-100 (0.01%) solution for 10 minutes. Dosimeter samples were separately packed and deep frozen after interim storage in cool boxes during the field phase. Aliquots of the DFR wash solutions were stored in cool boxes until deep freeze which was maintained until analysis. Further information is provided in the detailed study summaries (Appendix A) of the BROV report.

Environmental (weather) monitoring (non-GLP)

Environmental parameters (air temperature, relative humidity and rainfall) were recorded at each site during the study period (i.e. from the first application to the final exposure and/or DFR sampling event). In addition, weather records covering the study period were provided from the nearest official meteorological station which were usually within a 25 km range from the study location. Further information is provided in the detailed study summaries (Appendix A) of the BROV report.

Methods of analysis

The analytical methods for each active substance were reported in the individual study reports (with additional confirmatory information being requested from the study owner when clarification was required during the review by the UK HSE). These methods have been assessed to ensure that they were conducted in accordance with SANCO/3029/99 rev.4 7 and the method validation is reported in the detailed study summaries (Appendix A) of the BROV report. In all studies dosimeter extracts and DFR samples were analyzed by means of HPLC-MS/MS.

Results

The BROV re-entry database was compiled by the BROV WoG from the original study reports and has been validated by the UK HSE, key data from each study report has been entered into a MS Excel workbook (the BROV re-entry database) to allow calculations to be carried out in the same way for each study and to derive overall TC values. The following checks were made:

- All non-calculated values and information accurately reflect the contents of the study reports
- Values reported below the limit of quantification (LOQ) or limit of detection (LOD) have been correctly assigned the relevant LOQ and LOD values for each active substance and sampling matrix
- The relevant recovery adjustments have been made to the exposure and DFR measurements when required
- All formulae and calculated values are correct

Procedural recoveries and method validation

All procedural recoveries were within the acceptable range for method validation of 70-110% with RSDs within the acceptable limit of 20%. One exception was for a value of 115% for one fortification level of the hand wash solution in study 6. All methods of extraction and analysis were checked and confirmed to be acceptable. Full information is provided in the detailed study summaries (Appendix A) of the BROV report.

LOQ and LOD

LOQ (and, where reported, the LOD) values for each analyte and sampling matrix is summarized in Table 5 below. Further information is provided in the detailed study summaries (Appendix A) of the BROV report.

Table 5: LOQ and LOD values in BROV re-entry studies for dosimeters and DFR samples

<table>
<tr><th colspan="7">LOQ and LOD µg/sample</th></tr>
<tr><td colspan="2">Study</td><td>1</td><td>2 and 3</td><td>4 and 5</td><td>6 and 7</td><td>8</td></tr>
<tr><td colspan="2">Analyte</td><td>Iprovalicarb</td><td>Dimethomorph
Dithianon</td><td>Pyrimethanil</td><td>Fenbuconazole</td><td>Iprovalicarb</td></tr>
<tr><td rowspan="3">Outer layer</td><td>LOQ</td><td>10</td><td>0.01</td><td>0.01</td><td>7.5</td><td>0.5</td></tr>
<tr><td>LOD</td><td>Not stated</td><td>0.003</td><td>0.002</td><td colspan="2">Not stated</td></tr>
<tr><td>Sample</td><td>300 cm^2</td><td>100 cm^2</td><td>100 cm^2</td><td>Whole section</td><td>100 cm^2</td></tr>
<tr><td rowspan="3">Mid layer</td><td>LOQ</td><td>1.0</td><td colspan="4" rowspan="3">Not applicable</td></tr>
<tr><td>LOD</td><td>Not stated</td></tr>
<tr><td>Sample</td><td>300 cm^2</td></tr>
<tr><td rowspan="3">Inner layer</td><td>LOQ</td><td>0.5</td><td>0.01</td><td>0.01</td><td rowspan="3">Not applicable</td><td>0.5</td></tr>
<tr><td>LOD</td><td>Not stated</td><td>0.003</td><td>0.002</td><td>Not stated</td></tr>
<tr><td>Sample</td><td>300 cm^2</td><td>100 cm^2</td><td>100 cm^2</td><td>100 cm^2</td></tr>
<tr><td rowspan="3">Gloves</td><td>LOQ</td><td>50</td><td>0.1</td><td colspan="2" rowspan="3">Not applicable</td><td>50</td></tr>
<tr><td>LOD</td><td colspan="2">Not stated</td><td>Not stated</td></tr>
<tr><td>Sample</td><td>1 glove</td><td>1 glove</td><td>1 glove</td></tr>
<tr><td rowspan="3">Hand wash</td><td>LOQ</td><td>0.1</td><td>1</td><td>1</td><td>15</td><td>0.2</td></tr>
<tr><td>LOD</td><td>Not stated</td><td>0.3</td><td>0.06</td><td colspan="2">Not stated</td></tr>
<tr><td>Sample</td><td>100 ml</td><td>1 litre</td><td>1 litre</td><td>1 litre</td><td>1 litre</td></tr>
<tr><td rowspan="3">Face wipes</td><td>LOQ</td><td>0.1</td><td>0.01</td><td>0.01</td><td>0.75</td><td>0.02</td></tr>
<tr><td>LOD</td><td colspan="2">Not stated</td><td>0.003</td><td>Not stated</td><td>Not stated</td></tr>
<tr><td>Sample</td><td>1 pad (100 cm^2)</td><td>2 pads (each 100 cm^2)</td><td>2 pads (each 100 cm^2)</td><td>2 pads (each 100 cm^2)</td><td>2 pads (each 100 cm^2)</td></tr>
<tr><td rowspan="3">Leaf disc wash</td><td>LOQ</td><td>0.01</td><td>10</td><td>10</td><td>50</td><td>2</td></tr>
<tr><td>LOD</td><td>Not stated</td><td>1.3</td><td>1.5</td><td colspan="2">Not stated</td></tr>
<tr><td>Sample</td><td>1 litre</td><td>1 litre</td><td>1 litre</td><td>1 litre</td><td>1 litre</td></tr>
</table>

Measured values between LOQ and LOD have been assigned a value equivalent to the LOQ and values reported as not detected (ND) were assigned a value equivalent to the LOD. Very few of the exposure measurements (7 face wipe samples in study 6) and none of the DFR measurements, other than untreated control (UTC) samples, were reported to be below the LOQ for the relevant analyte and matrix, and the above approach for assigning values has not had an influence on the calculated 75th and 95th percentile values.

Field recovery results of dosimeter samples

Exposure monitoring samples were corrected for incomplete recovery only when the field recovery for that matrix was <95% for the relevant fortification level at the respective site. In almost all cases untreated control samples had analytical findings below LOQ. Thus, no correction was required. In BROV study 4, residue levels were not reported for face-wipe controls or hand-wash controls and, in study 8, the actual residue levels were not reported for any of the control or fortified samples (only the percentage recovery was reported).

Field recovery results of DFR samples

DFR measurement samples were corrected for incomplete recovery only when the field recovery was <95% for the relevant fortification level at the respective site. There was often considerable variation in residues between the control replicates at each site although some field recovery values were adjusted for low levels of residues detected in untreated control samples. Nevertheless, the BROV WoG concluded that there was no relevant impact on DFR calculations but only served to reduce reported high recovery levels (some of these > 100%) to more realistic levels. Therefore, this approach of applying a correction to high recoveries in the fortified samples if residues were detected in the corresponding untreated control samples was considered appropriate by the BROV WoG. For BROV studies 7 and 8 only summaries of recovery results were reported which was considered by the BROV WoG to be acceptable.

Travel recovery samples

Travel recovery values were not generated in each study, and when reported, not done for all matrices and/or spiking levels. They were usually slightly higher than field spike recovery samples as there was no exposure to ambient field conditions for the time of re-entry works. Mean recoveries for transit samples were within 70 to 110% of the fortification dose and mean RSD values were <20% in all studies.

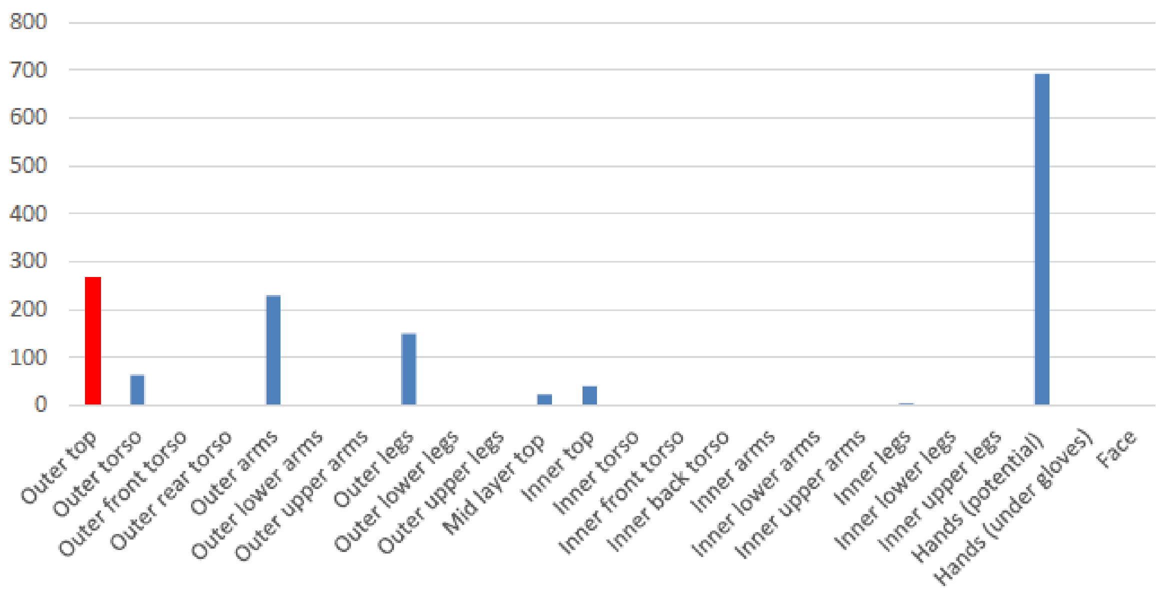
Environmental monitoring (weather data)

Data on air temperature, relative humidity and rainfall recorded at each site during the trial period did not indicate any adverse conditions likely to affect the study outcome. Similar evidence was provided by additional data from the nearest official meteorological station used in some studies. No rainfall occurred between the exposure and corresponding DFR sampling dates when these dates were not the same in the paired studies (study pairs 2 & 3 and 4 &5).

Exposure results

The results of individual re-entry exposure studies (1, 2, 4, 6 and 8) were expressed as mean values (where necessary corrected for field spike recoveries) for the individual dosimeters chosen in each study and type of operation performed (i.e. hand harvesting, pruning & tying, pruning and training, shoot lifting & pruning). The mean results as shown below were not normalized for application rates thus giving an indication for exposure distribution but no comparison of absolute exposure levels. In the bar charts for studies 1, 2, 4, 6 and 8 analytical findings of individual dosimeter sections are presented by blue bars, totals for a region of the body by red bars and (where relevant) sub-totals for smaller regions by green bars.

Figure 1. Study 1: Hand harvesting
Mean exposure (µg active substance)



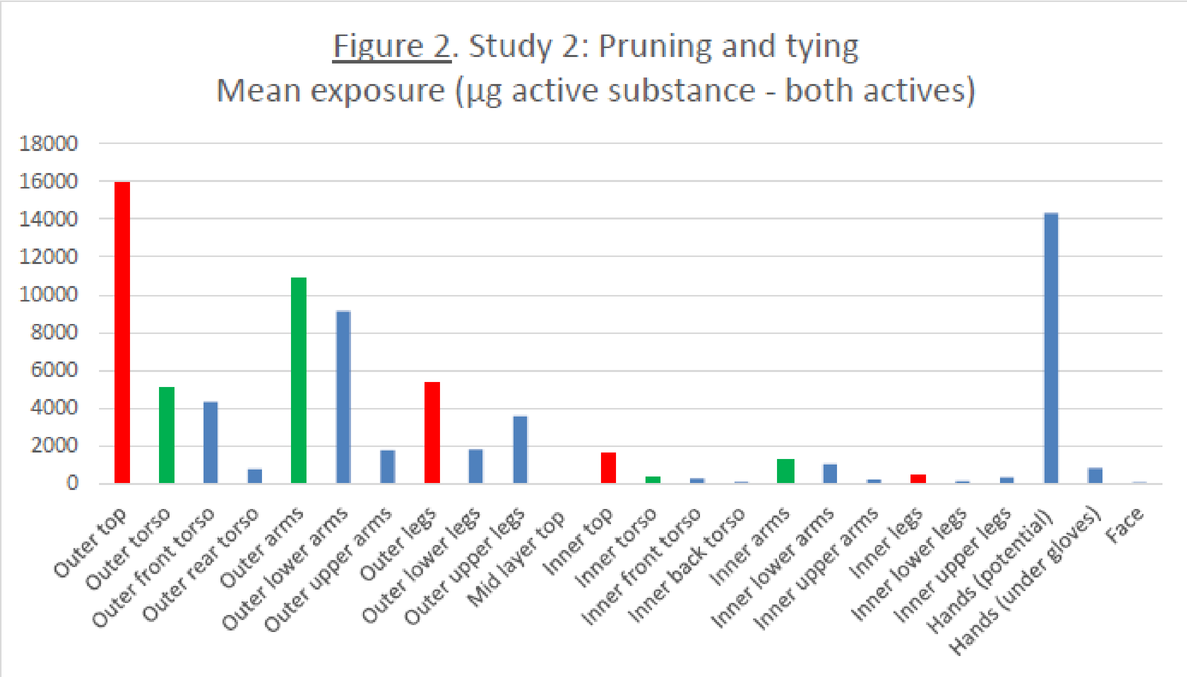


Figure 2. Study 2: Pruning and tying
Mean exposure (µg active substance - both actives)
18000
16000
14000
12000
10000
8000
6000
4000
2000
0
Outer top
Outer torso
Outer front torso
Outer rear torso
Outer arms
Outer lower arms
Outer upper arms
Outer legs
Outer lower legs
Outer upper legs
Mid layer top
Inner top
Inner torso
Inner front torso
Inner back torso
Inner arms
Inner lower arms
Inner upper arms
Inner legs
Inner lower legs
Inner upper legs
Hands (potential)
Hands (under gloves)
Face

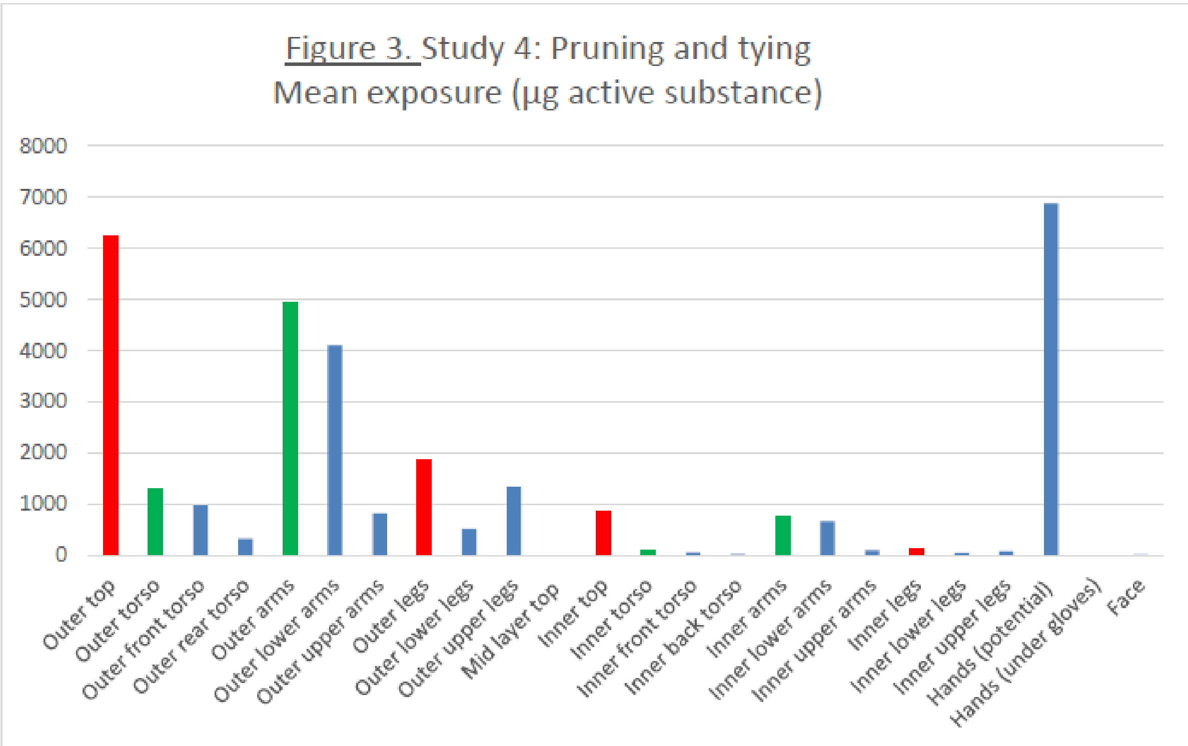


Figure 3. Study 4: Pruning and tying
Mean exposure (µg active substance)
8000
7000
6000
5000
4000
3000
2000
1000
0
Outer top
Outer torso
Outer front torso
Outer rear torso
Outer arms
Outer lower arms
Outer upper arms
Outer legs
Outer lower legs
Outer upper legs
Mid layer top
Inner top
Inner torso
Inner front torso
Inner back torso
Inner arms
Inner lower arms
Inner upper arms
Inner legs
Inner lower legs
Inner upper legs
Hands (potential)
Hands (under gloves)
Face

Figure 4. Study 6: Pruning and training
Mean exposure (µg active substance)

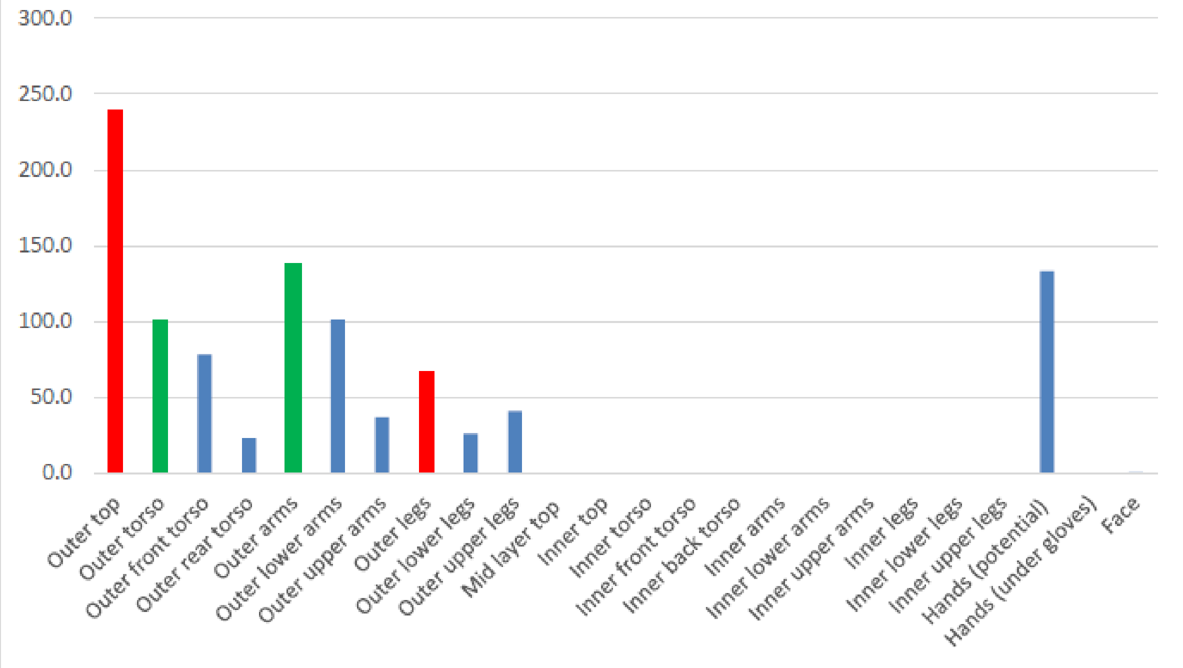
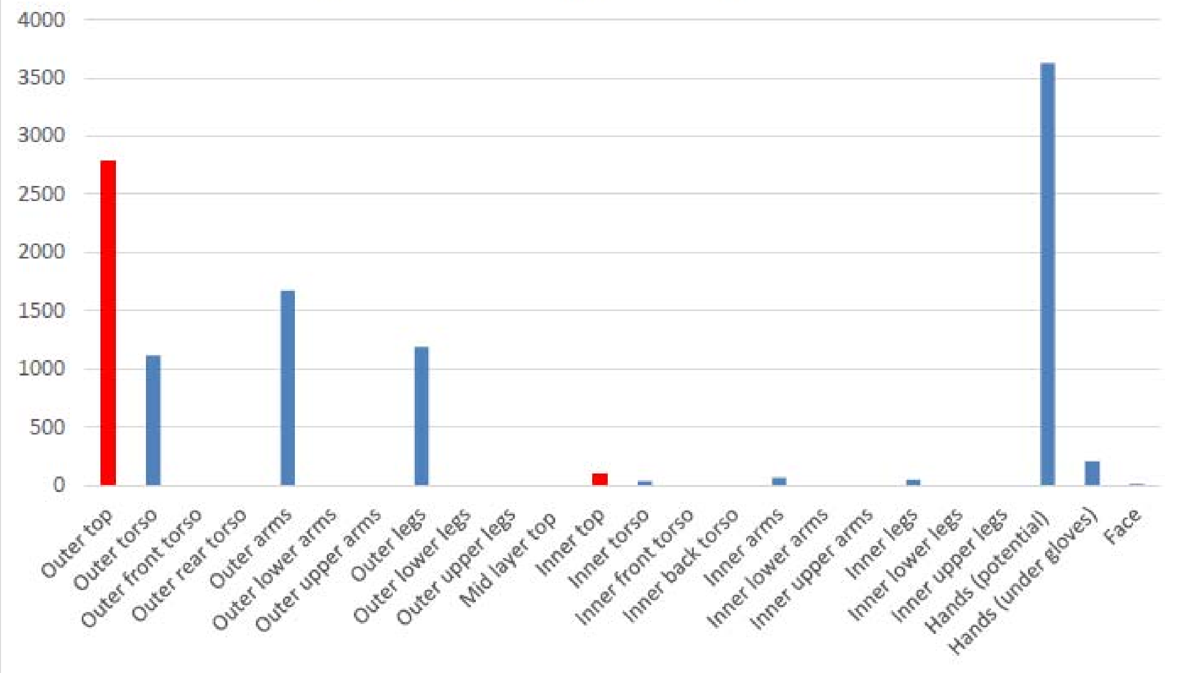


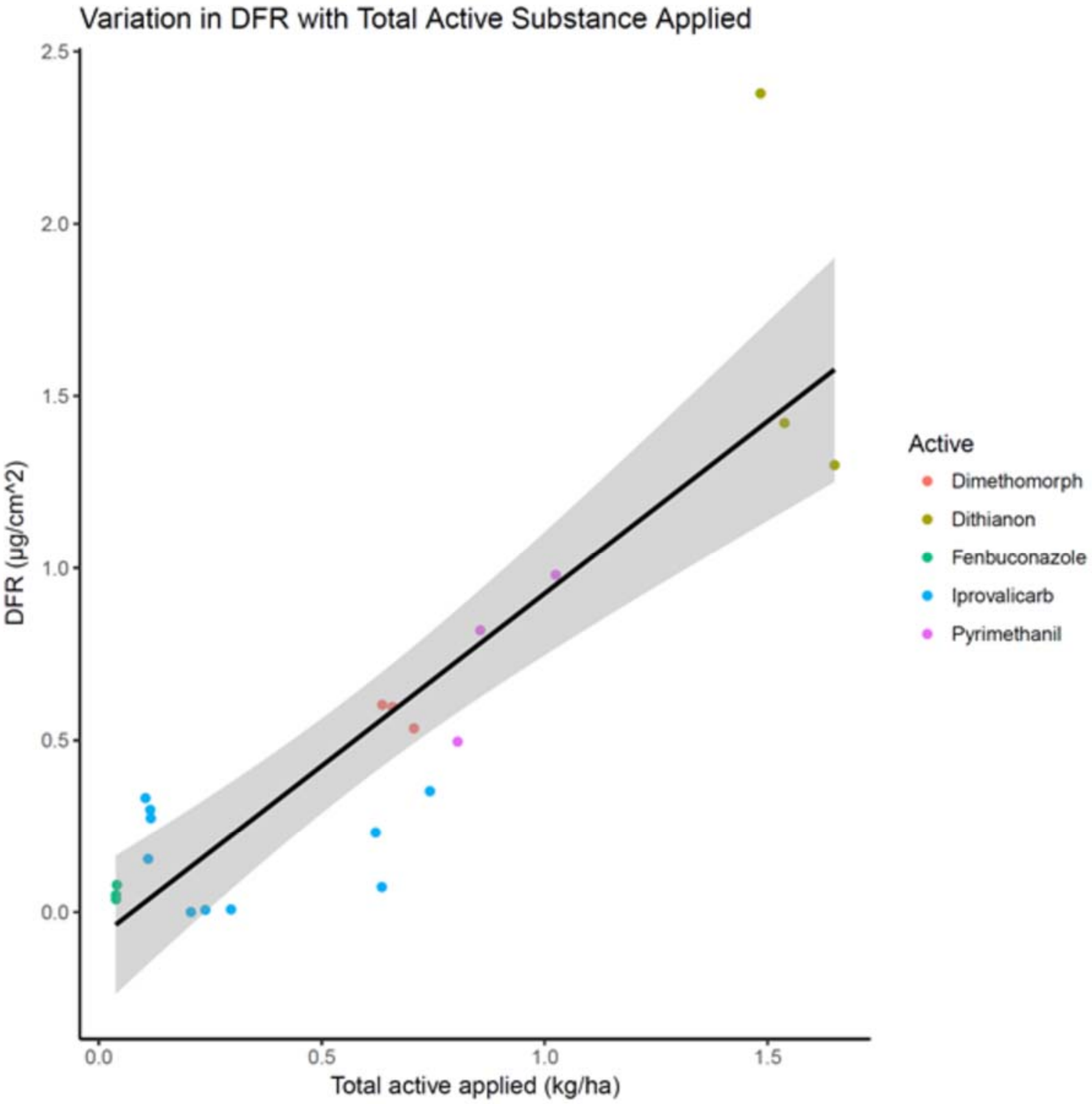
Figure 5. Study 8: Shoot lifting and pruning
Mean exposure (µg active substance)



Overall, exposure levels were highest in the outer top ranging from about 250 to 16000 µg/operator and in hands (potential) ranging from about 140 to 14000 µg/operator. Exposure levels were lowest in study 6 (likely to be associated with low application rates of active substance) and in study 1 (possibly associated with extended period between terminal application and re-entry for harvest of the grapes).

Results of dislodgeable foliar residues (DFR)
In general, DFR values showed a good correlation with the application rate of the active substance as shown in Figure 6

Figure 6: Relationship between DFR (µg/cm^2) and total active substance applied (kg/ha); solid line shows linear regression and shading indicates 95 percent confidence interval of the mean



If potential body exposure (Figure 7) and actual body exposure (Figure 9) as well as and potential hand exposure (Figure 8) and actual hand exposure (Figure 10) are compared to measured DFR values the data suggest a good correlation. Given the various re-entry activities or combination of tasks Figures 7 to 10 suggest that the measured exposure levels may be more influenced by the level of DFR in each study than the nature of the task performed.

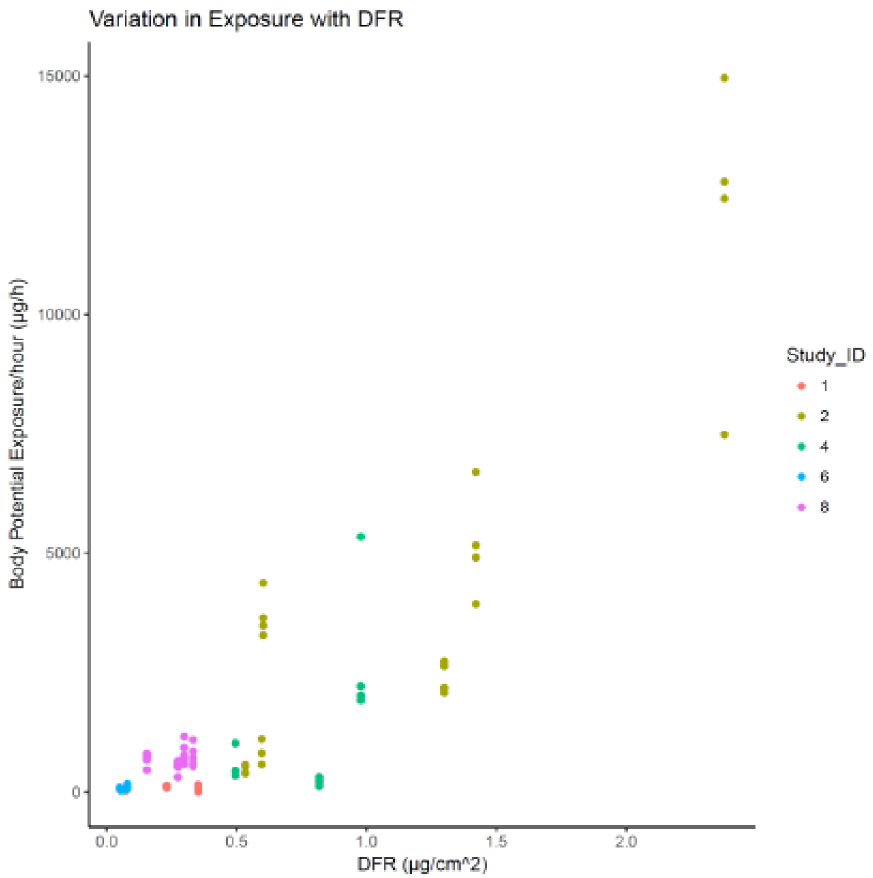
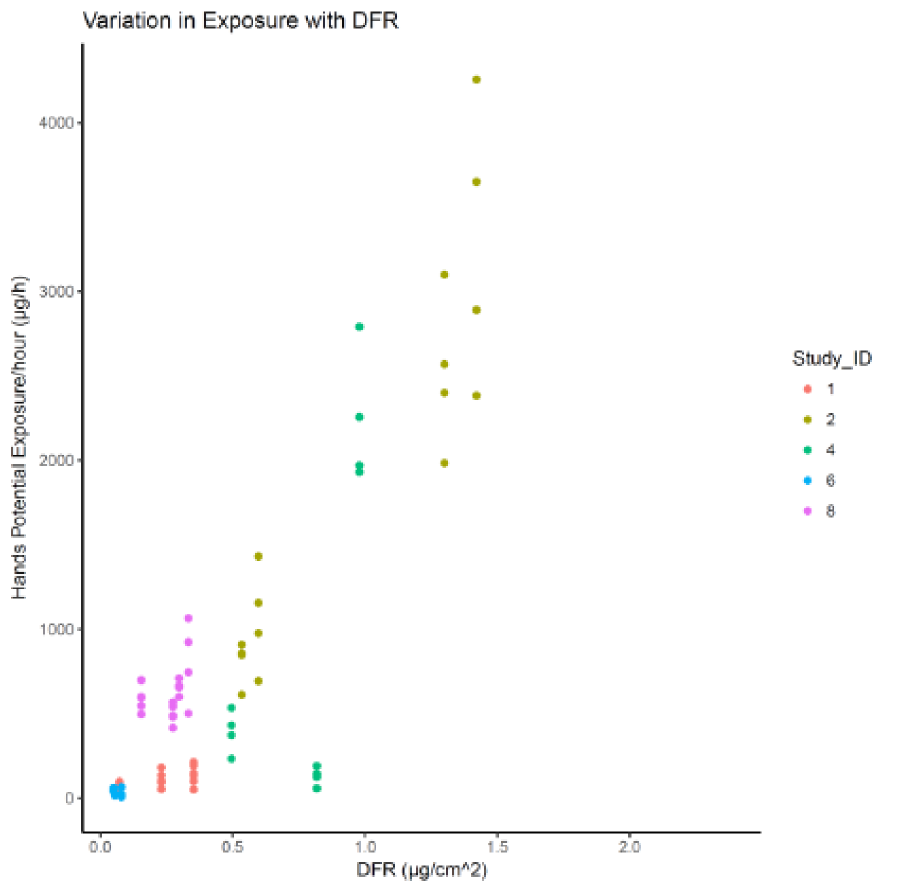
Figure 7: Potential body exposure per hour (µg/h) and DFR (µg/cm^2)	**Figure 8: Potential hand exposure per hour (µg/h) and DFR (µg/cm^2)**
	

Figure 9: Actual body exposure per hour (μg/h) and DFR (μg/cm^2)

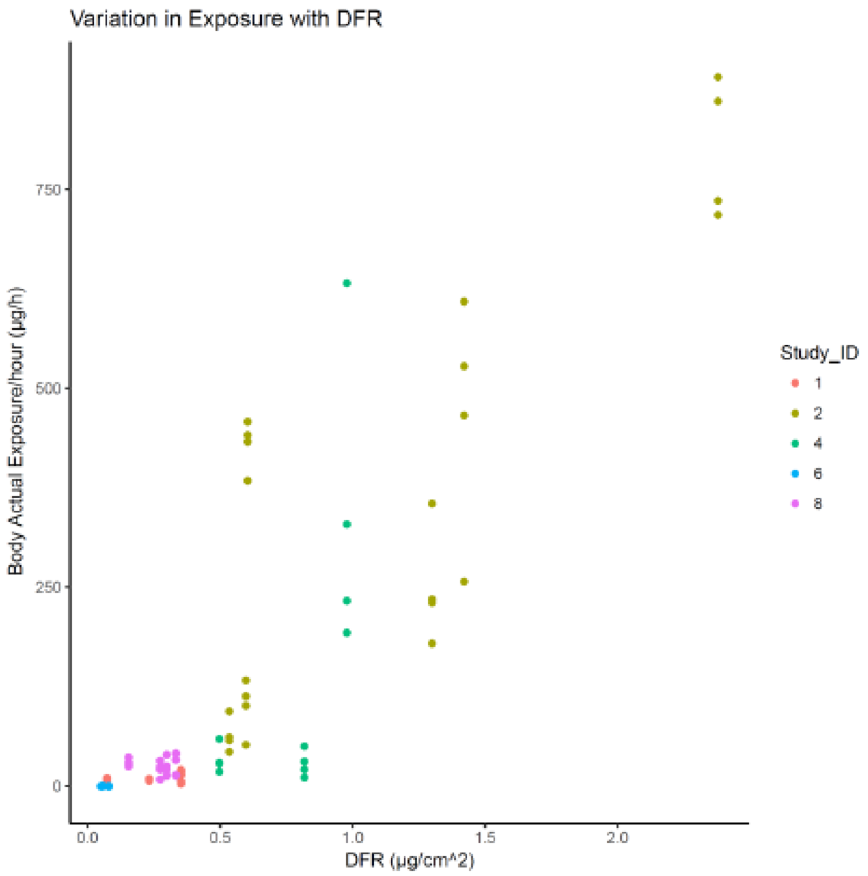
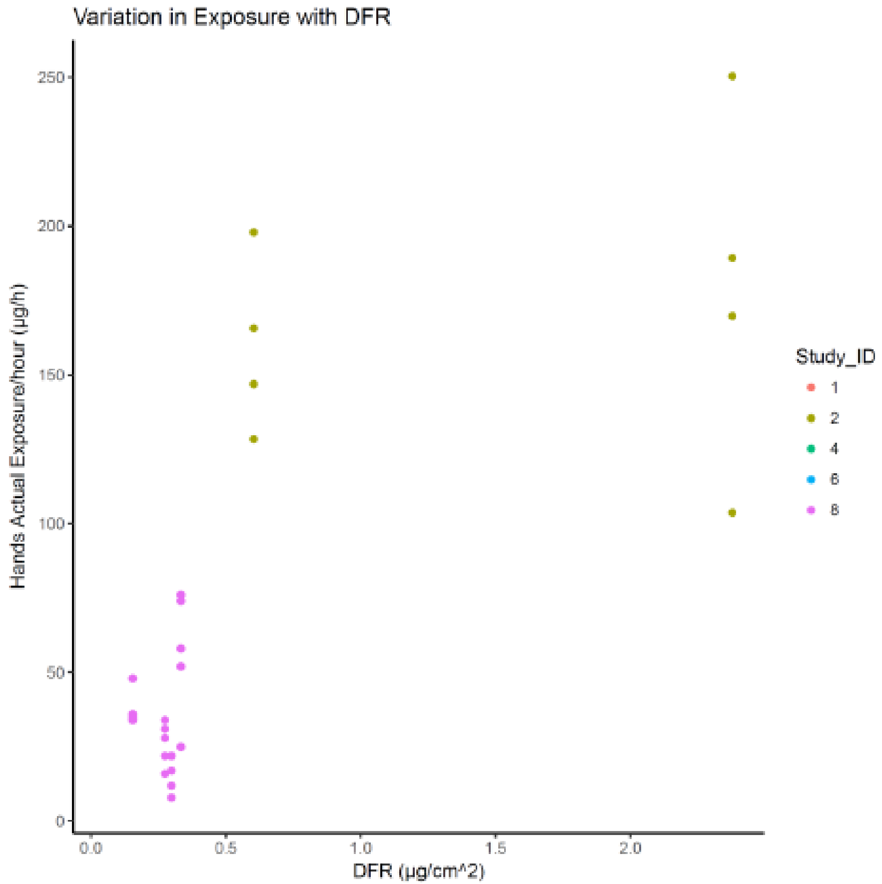


Figure 10: Actual hand exposure per hour (μg/h) and DFR (μg/cm^2)



Transfer coefficient values

The following approach was chosen by the BROV WoG: TC values for each study subject were calculated by adding the exposure measurements on the relevant dosimeters, dividing the total exposure (µg of active substance per person) by the duration of the exposure monitoring (hours) for that study subject, and then dividing the total exposure per hour for each subject by the mean DFR (µg of active substance per cm^2 of leaf surface) measured in the concurrent DFR study for the matching site. TC values for each study subject were calculated in this way (subject to the availability of the relevant dosimeter measurements) for:

- Potential dermal exposure (PDE) to the body (less hands)
- PDE to the body (including hands)
- PDE to the hands
- Actual dermal exposure (ADE) to the body (less hands)
- ADE to the body (including hands)
- ADE to the hands (under gloves)

Based on these sets of individual TC values overall 75th and 95th percentile values were calculated for potential and actual body and hand exposure. Additional 75th and 95th percentile TC values were calculated for the various tasks monitored in the separate studies as summarized in Table 6. The method of calculation described above means that the percentile TC values for the body and hands may not add up to the corresponding total TC values because the latter have been calculated from the sum of all relevant dosimeters for each individual study subject, whereas a given percentile value for body exposure and hand exposure will not necessarily relate to the same individual study subject. The total (body and hands) TC values for potential exposure from the BROV studies (highest 95th percentile value = 9000 cm^2/h) are lower than the current default TC value in the EFSA Guidance Document of 30000 cm^2/h).

Table 6: TC values derived from BROV study set

Transfer Coefficient (cm^2/h)						
Task	**Potential exposure**			**Actual exposure**		
	Body	**Hands**	**Total[1]**	**Body[2]**	**Hands[3]**	**Total[1]**
Overall, 75th percentile	2500	2100	4300	190	220	410
Overall, 95th percentile	5400	3300	7900	640	300	990
Harvesting, 75th percentile	560	800	1500	60		
Harvesting, 95th percentile	910	1300	1800	130		
Pruning/training, 75th percentile	2900	1900	3800	340	250	980
Pruning/training, 95th percentile	5900	2600	6500	720	310	1000
Pruning/shoot lifting, 75th percentile	3400	3200	6100	140	220	350
Pruning/shoot lifting, 95th percentile	4900	3900	9000	200	230	420
All maintenance, 75th percentile	3200	2200	4500	250	220	410
All maintenance, 95th percentile	5700	3500	8300	660	300	990

[1] The percentile TC values for the body and hands may not add up to the corresponding total TC values because the latter are calculated from the sum of all relevant dosimeters for each individual study subject, whereas a given percentile value for body exposure and hand exposure will not necessarily relate to the same individual study subject.
[2] Body exposure beneath a single layer of long-sleeved and long-legged clothing.
[3] Actual hand exposure under work gloves (partial nitrile).

The compilation of transfer coefficients for the scenarios of clothed body and bare hands as well as clothed body and protected hands is shown in Table 7 below. Gloves (partial nitrile work gloves) were worn in study 8 (20 study subjects) and were also worn (but not monitored) at just one site in study 2 (4 study subjects). The BROV WoG was confident that the type of gloves used in this study was representative of those typically worn when carrying out similar tasks. An EN Standard is under development for this type of glove which, if agreed, will allow the appropriate type of glove to be specified and will offer re-assurance that the predicted (or appropriate default) levels of protection can be achieved. In study 8, the transfer/penetration values for these gloves, based on a comparison of the hand TCs (presented above) and supported by the exposure measurements, was 6 to 7% and this is in line with the EFSA calculator assumption of 10% transfer of foliar residues through gloves. Therefore, the BROV WoG concluded that if similar gloves were worn for other re-entry tasks in grapes, it would be appropriate to apply a default protection factor of 90% (i.e. 10% penetration and transfer) to the TC for unprotected hands for those tasks, and this 90% protection factor has been applied to derive the scenario of clothed body in combination with protected hands.

Table 7: TC values derived from BROV study set for scenarios of clothed body & bare hands and clothed body & gloved hands

Transfer Coefficient (cm²/h)					
Task	TC for clothed body and bare hands			TC for clothed body and gloved hands[1]	
	TC for ADE body *A*	TC for PDE hands *B*	TC for clothed body & bare hands *A + B*	TC for gloved hands *C*	TC for clothed body & gloved hands *A + C*
Overall, 75th percentile	190	2100	2300	210	400
Overall, 95th percentile	640	3300	3600	330	970
Harvesting, 75th percentile	60	800	920	80	140
Harvesting, 95th percentile	130	1300	1400	130	260
Pruning/training, 75th percentile	340	1900	2300	190	530
Pruning/training, 95th percentile	720	2600	3200	260	980
Pruning/shoot lifting, 75th percentile	140	3200	3300	320	460
Pruning/shoot lifting, 95th percentile	200	3900	4100	390	590
All maintenance, 75th percentile	250	2200	2600	220	470
All maintenance, 95th percentile	660	3500	3900	350	1000
[1] Considering 90% protection by partial nitrile gloves based on unprotected hand exposure values					

The compilation of transfer coefficients for the scenarios of lightly clothed body (e.g. shorts and T-shirt) in combination with bare hands as well as lightly clothed body in combination with protected hands is shown in Table 8 below. The derivation of these TC values has been made based on the assumption that light clothing would only provide limited protection and the potential dermal exposure estimate will therefore suggest a conservative approach for this scenario.

Table 8: TC values derived from BROV study set for scenarios of lightly clothed body & bare hands and clothed body & gloved hands

Transfer Coefficient (cm²/h)					
Task	TC for lightly clothed body and bare hands			TC for lightly clothed body and gloved hands[1]	
	TC for PDE body *D*	TC for PDE Hands *B*	TC for lightly clothed body & bare hands[§] *D + B*	TC for gloved hands *C*	TC for lightly clothed body & gloved hands *D + C*
Overall, 75th percentile	2500	2100	4300	210	2700
Overall, 95th percentile	5400	3300	7900	330	5700
Harvesting, 75th percentile	560	800	1500	80	640
Harvesting, 95th percentile	910	1300	1800	130	1000
Pruning/training, 75th percentile	2900	1900	3800	190	3100
Pruning/training, 95th percentile	5900	2600	6500	260	6200
Pruning/shoot lifting, 75th percentile	3400	3200	6100	320	3700
Pruning/shoot lifting, 95th percentile	4900	3900	9000	390	5300
All maintenance, 75th percentile	3200	2200	4500	220	3400

All maintenance, 95th percentile	5700	3500	8300	350	6000
[1] Considering 90% protection by partial nitrile gloves based on unprotected hand exposure values § The percentile TC values for the body and hands may not add up to the corresponding total TC values because the latter are calculated from the sum of all relevant dosimeters for each individual study subject, whereas a given percentile value for body exposure and hand exposure will not necessarily relate to the same individual study subject					

Proposals for transfer coefficient values

The results as shown in the tables above suggest that crop maintenance activities (e.g. pruning/training, pruning/shoot lifting) result in higher TC values as compared to harvest activities. The BROV WoG concluded that it is appropriate to treat all studies as a single dataset and, in line with the current TC values for grapes recommended by the EFSA guidance document[1], propose TC values covering all re-entry tasks in grapes. As re-entry operations may also be performed under hot conditions workers may habitually wear minimal clothing. This would suggest a light clothing TC in addition to the TC derived for the working clothing scenario. The proposed TC values are summarized in Table 9 below.

Table 8: Proposed transfer coefficients for re-entry operations in grapes

Proposed transfer coefficient (cm²/h)					
Clothing and PPE	**TC for body**		**TC for hands**		**Total TC**
	PDE	**ADE[1]**	**PDE**	**Gloves[2]**	
Light clothing, no gloves 75th centile estimate	**3400**	**-**	**3200**	**-**	**6600**
Light clothing, no gloves 95th centile estimate	**5900**	**-**	**3900**	**-**	**9800**
Light clothing, work gloves 75th centile estimate	**3400**	**-**	**-**	**320**	**3700**
Light clothing, work gloves 95th centile estimate	**5900**	**-**	**-**	**390**	**6300**
Full-length clothing, no gloves 75th centile estimate	**-**	**340**	**3200**	**-**	**3500**
Full-length clothing, no gloves 95th centile estimate	**-**	**720**	**3900**	**-**	**4600**
Full-length clothing, work gloves 75th centile estimate	**-**	**340**	**-**	**320**	**660**
Full-length clothing, work gloves 95th centile estimate	**-**	**720**	**-**	**390**	**1100**
[1] Single layer of long-sleeved and long-legged clothing [2] Partial nitrile work gloves (10% penetration and transfer assumed)					

References

[1] EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874

[2]: OECD (Organisation for Economic Co-operation and Development), 1997. Guidance document for the conduct of studies of occupational exposure to pesticides during agricultural application. Series on testing and assessment No. 9. GD (97) 148

[3]: The US EPA Office of Pesticide Programmes Series 875 Occupational and Residential Exposure Test Guidelines. Group B – Post-application Exposure Monitoring Test Guidelines. Part B, Chapter 3: Dislodgeable Foliar Residue Dissipation: Agricultural Guideline 875.2100. Part C: Quality assurance/Quality Control (QA/QC)

[4]: European Commission SANCO/3029/99 rev 4. European Commission guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414