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RESEARCH ARTICLE

Protection by ordinary light clothing against pesticide spray drift for bystanders and residents

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Abstract

There are stringent EU regulatory requirements to assess pesticide exposure to bystanders and residents to direct spray drift. A "light clothing" adjustment factor (AF) of 0.82 is applied in the exposure assessment, based on simple assumptions for covered body surface and penetration through clothing. To assess the appropriateness of the AF, we collated data from 32 field studies. The mean and 25th percentile % reduction from ordinary light clothing ("reduction %") in children and adults for all crops and standard and drift-reducing nozzles were 42.7% and 36.2%, resulting in AF of 0.573 and 0.638, respectively. Sources of variation were investigated, e.g. crop type, leaf coverage, buffer, spray pressure, and nozzle type, which indicated that reduction % could be impacted by several conditions. The reduction % is similar between crops; therefore, a single AF value covering all crops can be derived. One exception was for early-stage vineyard scenarios (the reduction % is lower (27%) than late stage (42–47%)) and could be considered individually to avoid unnecessary conservatism for the other scenarios. This evaluation demonstrates the current AF to be overly precautionary, and a more realistic, exposure scenario-relevant value could be applied for bystander/resident risk assessments.

Keywords Direct spray drift · Adjustment factor · Field studies · Plant protection products · Risk assessment · Bystander · Residents · Non-dietary exposure

1 Introduction

For the registration of plant protection products (PPPs) in the European Union (EU), there are stringent regulatory requirements for the assessment of pesticide exposure to bystanders and residents. Amongst the 4 exposure scenarios (vapour exposure, surface deposits, entry into treated crop, and oral exposure via hand-mouth-transfer), a dermal exposure to direct spray drift is usually predominant (EFSA 2014; EFSA et al. 2022). A typical example for such a scenario is exposure via spray drift while walking in close proximity to a field that is treated with a PPP at the same time. Although bystander and resident risk assessments do not consider any professional personal protective equipment (PPE), it is reasonable to assume that ordinary "light" or "minimal" clothing can provide a certain level of protection. Here, we considered ordinary "light" or "minimal" clothing according to the EFSA guidance documents. The regulatory risk assessment guidance assumes 18% reduction in exposure due to minimal clothing and applies a "light clothing" adjustment factor (AF) by multiplying the exposure via spray drift by 0.82. However, here, the AF for ordinary (i.e. light and minimal) clothing was derived from operator exposure data and not actual bystander exposure data (EUROPOEM 1996; EFSA 2014). This introduced uncertainty to the derived AF because more relevant data were missing at the time of the publication of the EFSA guidance. As recommended by the EFSA guidance (EFSA 2014), further data and/or information is necessary in order to produce more realistic exposure assessments.

The data behind the current default AF assumptions in the EFSA guidance (EFSA 2014) and actual dermal exposure estimation consider (1) the penetration through work clothing and (2) the body area covered by clothing. Normal work wear is defined as clothes that cover arms, body and legs by coveralls or long-sleeved jackets/shirts

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and trousers made of dense weave cotton or cotton/polyester material (EFSA 2014; EFSA et al. 2022), whereas ordinary "light" or "minimal clothing" refers to t-shirts and shorts, with the arms and legs uncovered. In the EFSA guidance (EFSA 2014), penetration through light clothing is assumed to be 50%, and a reference is made to the EUROPOEM (1996) report. However, EUROPOEM (1996) noted that in the majority of cases, the reduction coefficients are in the range of 0.02–0.2 (garments), i.e. penetration of 2–20% through clothing. This reduction has been applied for estimates of potential dermal exposure arising from spray drift only. It should be noted that the proposed default reduction coefficient in the EUROPOEM (1996) report was merely a preliminary estimation derived from operator exposure data, i.e. not wearing any form of PPE. Notably, the draft report was never finalized, moreover, it suggested that the whole subject needs further consideration, e.g. by examining the available exposure studies which provide data for external contamination and contamination beneath clothing. Later, in the EUROPOEM report (2002), it was reiterated that due to the preliminary nature of reduction factors, a more detailed evaluation is required. Additionally, the same protection value of 50% has been assumed by ECHA for non-professionals (ECHA 2015).

The second assumption in the EFSA guidance (2014) is the body area covered by clothing. It considers only the coverage of the trunk area (i.e. bosom, neck, shoulders, abdomen, back, genitals and buttocks), while the EUROPOEM reports suggest considering minimal or light clothing (EUROPOEM 1996, 2002). According to EFSA (2014), the body part covered by clothing is the trunk, and the percentage of a total body surface are calculated as follows:

$$\%\text{Total body surface} = \frac{\text{trunk}\,(\text{cm}^2)}{\text{total body area}\,(\text{cm}^2)} \times 100$$

This results in an average covered area across all ages of 38.17% using values according to EFSA (2014) guidance, and 39.40% using values according to the EFSA 2022 draft guidance (EFSA et al. 2022) (the values and calculations for different ages are shown in Supplementary Table S1). The assumptions on covered body surface area (i.e. trunk vs. t-shirt and shorts) and the subsequent AF have been commented during the open call for the EFSA 2022 guidance (EFSA et al. 2022); however, without further data, EFSA have maintained the same approach for the 2022 guidance.

As a consequence of conservative considerations regarding the clothing, penetration, and subsequently applied AFs (multiplication of worst-case factors or assumptions), the bystander/resident exposure to spray drift has become one of the main concerns in non-dietary risk assessments. This is a similar situation to the impact of the EFSA guidance (EFSA 2014) on worker re-entry exposure estimations due to revised assumptions (Kluxen et al. 2021).

Therefore, the objective of this study was to present data that may allow the refinement of the current default AF for ordinary clothing for bystanders and residents, and thus refine product specific risk assessments. To this end, member companies of the industry association, CropLife Europe (CLE), have conducted 32 GLP studies (35 trials) to result in a scenario-specific dataset which was compared to the currently used preliminary value assumed from operator exposure data (EUROPOEM 1996; 2002).

2 Materials and methods

A dataset has been compiled from 32 GLP studies (35 trials) which were conducted by CLE member companies between 2011 and 2019 to refine product-specific bystander and resident risk assessments.

2.1 Locations and application details

The studies were conducted in different locations across Europe under realistic field conditions. The details of the main application parameters (e.g. crop type, application method, nozzle type, etc.), conditions (i.e. wind speed), and sampling setup (i.e. replicates, distances) of each trial are summarized in Table 1.

2.2 Sampling setup and measurements

A total of 742 replicates were used in the studies, with equal numbers of adult and child mannequins (adults body height ~ 1.88 m and children ~ 1 m), and 16 to 54 replicates for each trial. Mannequins were always positioned facing the treated area at various distances (high crops: 5, 10, and 15 m; low crops 2, 3, 5, 8, 10, 13 m) downwind from the zero metre position. For a set up with multiple rows of mannequins, to avoid any possible interference of the drift, the mannequins in the second row were off-set by 1 m from the mannequins in first row, and the same for the third row. The zero metre position was defined for high crops as half the row width beyond the last row, for low crops as the edge of the crop, end of the spray boom or last nozzle plus half the nozzle spacing (Supplementary Fig. S1).

In all studies, dermal exposure was determined using whole body dosimetry according to the approach described in OECD Test Guideline No. 9 (OECD 1997) and OPPTS 875.1100 (US EPA 1996). The test system comprised the dermal exposure sampling media worn by adult and child

Table 1 Field conditions and physico-chemical properties of active ingredients used in the 35 trials

	Crop	BBCH stage	Country	Indication	Formulation type	Molecular weight of AI, g/mol	Log Pow of AI	Water solubility of AI, mg/L	Application method	Field size (m^2)	Water volume (L/ha)	Spray pressure (bar)	Nozzle type	Normal nozzles or DRN	Number of nozzles	Driving speed (km/h)	Replicates (total, adult, child)	Distance from zero line (m)	Average wind speed (m/s)
Trial 1	Vineyard	13	Spain	Fungicide	SC	308.14	4.66 at 20 °C, pH 6.6	0.047 at pH 7	High crop trailed sprayer (broadcast air-assisted sprayer)	7800	346	10	Albuz ATR (red) hollow cone 80° angle	Normal	4	6.48	18, 9, 9	5, 10, 15	3.34
Trial 2	Pome fruit	53–55	Spain	Fungicide	WG	313.3	3.4 at 25 °C, pH independent	2 at 20 °C, pH independent	High crop trailed sprayer (broadcast air-assisted sprayer)	14,400	610	10	Albuz ATR (red) hollow cone 80° angle	Normal	12	6.3	18, 9, 9	5, 10, 15	2.97
Trial 3	Pome fruit	91	Italy	Fungicide	WG	313.3	3.4 at 25 °C, pH independent	2 at 20 °C, pH independent	High crop trailed sprayer (broadcast air-assisted sprayer)	11,000	1091	22.5	Albuz Red ATR-80	Normal	10	4	18, 9, 9	5, 10, 15	1.19
Trial 4	Vineyard	81	Italy	Fungicide	SC	308.14	4.66 at 20 °C, pH 6.6	0.047 at pH 7	High crop trailed sprayer (broadcast air-assisted sprayer)	7200	597	15	Albuz Brown ATR 80	Normal	8	1.9	18, 9, 9	5, 10, 15	0.3
Trial 5	Pome fruit	87	Spain	Fungicide	WG	313.3	3.4 at 25 °C, pH independent	2 at 20 °C, pH independent	High crop trailed sprayer (broadcast air-assisted sprayer)	7800	962	7.5	Albuz Orange ATR-80	Normal	14	4.7	18, 9, 9	5, 10, 15	1.3
Trial 6	Vineyard	81	Spain	Fungicide	SC	308.14	4.66 at 20 °C, pH 6.6	0.047 at pH 7	High crop trailed sprayer (broadcast air-assisted sprayer)	10,900	872	8	Albuz Red ATI 80–04	Normal	8	3.7	18, 9, 9	5, 10, 15	1.19

Table 1 (continued)

	Crop	BBCH stage	Country	Indication	Formulation type	Molecular weight of AI, g/mol	Log Pow of AI	Water solubility of AI, mg/L	Application method	Field size (m^2)	Water volume (L/ha)	Spray pressure (bar)	Nozzle type	Normal nozzles or DRN	Number of nozzles	Driving speed (km/h)	Replicates (total, adult, child)	Distance from zero line (m)	Average wind speed (m/s)
Trial 7	Pome fruit	53	Italy	Fungicide	WG	313.3	3.4 at 25 °C, pH independent	2 at 20 °C, pH independent	High crop trailed sprayer (broadcast air-assisted sprayer)	11,000	1055	22.5	Albuz ATR-80	Normal	10	4	18, 9, 9	5, 10, 15	1.45
Trial 8	Vineyard	13–15	Italy	Fungicide	SC	308.14	4.66 at 20 °C, pH 6.6	0.047 at pH 7	High crop trailed sprayer (broadcast air-assisted sprayer)	12,000	150	9	Albuz Red ATR-80	Normal	4	1.6	18, 9, 9	5, 10, 15	1.96
Trial 9	Pome fruit	53	Spain	Fungicide	WG	313.3	3.4 at 25 °C, pH independent	2 at 20 °C, pH independent	High crop trailed sprayer (broadcast air-assisted sprayer)	7800	641	5.5	Albuz Orange ATR-80	Normal	14	4.7	18, 9, 9	5, 10, 15	1.84
Trial 10	Vineyard	13	Spain	Fungicide	SC	308.14	4.66 at 20 °C, pH 6.6	0.047 at pH 7	High crop trailed sprayer (broadcast air-assisted sprayer)	10,900	569	8	Albus Red ATI 80–04	Normal	8	2.8	18, 9, 9	5, 10, 15	1.37
Trial 11	Pome fruit	81	Poland	Fungicide	WG	313.3	3.4 at 25 °C, pH independent	2 at 20 °C, pH independent	High crop trailed sprayer (broadcast air-assisted sprayer)	8300	605	20	Teejet/Conejet Green TXB800 15 VK	Normal	22	8.9	18, 9, 9	5, 10, 15	1.1
Trial 12	Pome fruit	81	Poland	Fungicide	WG	313.3	3.4 at 25 °C, pH independent	2 at 20 °C, pH independent	High crop trailed sprayer (broadcast air-assisted sprayer)	8400	824	4.5	Lechler Blue hollow cone TR 80–03 (TK 80-01C)	Normal	16	5.3	18, 9, 9	5, 10, 15	2.35

Table 1 (continued)

	Crop	BBCH stage	Country	Indication	Formulation type	Molecular weight of AI, g/mol	Log Pow of AI	Water solubility of AI, mg/L	Application method	Field size (m^2)	Water volume (L/ha)	Spray pressure (bar)	Nozzle type	Normal nozzles or DRN	Number of nozzles	Driving speed (km/h)	Replicates (total, adult, child)	Distance from zero line (m)	Average wind speed (m/s)
Trial 13	Pome fruit	53–55	Poland	Fungicide	WG	313.3	3.4 at 25 °C, pH independent	2 at 20 °C, pH independent	High crop trailed sprayer (broadcast air-assisted sprayer)	10,000	530	20	Teejet/Conejet 11 × Yellow TXB800 02VK; 11 × Green TXB800 15 VK	Normal	22	5.3	18, 9, 9	5, 10, 15	3.47
Trial 14	Vineyard	13–15	France	Fungicide	SC	308.14	4.66 at 20 °C, pH 6.6	0.047 at pH 7	High crop trailed sprayer (broadcast air-assisted sprayer)	15,900	140	2.4	Calvet 16/10 pastilles	Normal	8	3.5	18, 9, 9	5, 10, 15	2.12
Trial 15	Vineyard	81	France	Fungicide	SC	308.14	4.66 at 20 °C, pH 6.6	0.047 at pH 7	High crop trailed sprayer (broadcast air-assisted sprayer)	7400	122	2	Calvet 10/10 pastilles	Normal	8	4.7	18, 9, 9	5, 10, 15	1.81
Trial 16	Vineyard	81	France	Fungicide	SC	308.14	4.66 at 20 °C, pH 6.6	0.047 at pH 7	High crop trailed sprayer (broadcast air-assisted sprayer)	7500	213	10	Albuz—10 × ATR 80 Lilac at bottom and 10 × ATR 80 Brown at top	Normal	18	5.5	18, 9, 9	5, 10, 15	2.78
Trial 17	Oilseed rape	65	Germany	Insecticide	OD	252.73	1.26–1.4 at 20 °C	184 at pH 7	Field crop boom sprayer	11,200	200	2.6	XR 110–04	Normal	56	9	18, 9, 9	3, 8, 13	2.7
Trial 18	Oilseed rape	65	Germany	Insecticide	OD	252.73	1.26–1.4 at 20 °C	184 at pH 7	Field crop boom sprayer	11,200	200	2.6	AI 110–04	DRN	56	9	18, 9, 9	3, 8, 13	2.6
Trial 19	Winter wheat	55	Germany	Fungicide	EC	297.5 344.26 312.2	2.79–2.98 at 20 °C 3.82 at 20 °C, pH 7 3.04 at 22 °C	470 at 20 °C, pH 5 300 at 20 °C pH 8 51 at 20 °C	Field crop boom sprayer	2800	100	1.5	XR 110–03	Normal	56	10	54, 27, 27	2, 5, 8	2.3

Table 1 (continued)

	Crop	BBCH stage	Country	Indication	Formulation type	Molecular weight of AI, g/mol	Log Pow of AI	Water solubility of AI, mg/L	Application method	Field size (m^2)	Water volume (L/ha)	Spray pressure (bar)	Nozzle type	Normal nozzles or DRN	Number of nozzles	Driving speed (km/h)	Replicates (total, adult, child)	Distance from zero line (m)	Average wind speed (m/s)
Trial 20	Winter wheat	56	Germany	Fungicide	EC	297.5 344.26 312.2	2.79–2.98 at 20 °C 3.82 at 20 °C, pH 7 3.04 at 22 °C	470 at 20 °C, pH 5 300 at 20 °C, pH 8 51 at 20 °C	Field crop boom sprayer	2800	100	1.5	Lechler IDKN 120–03	DRN	56	10	54, 27, 27	2, 5, 8	2.9
Trial 21	Winter wheat	56	Germany	Fungicide	EC	344.26 312.2	3.82 at 20 °C, pH 7 3.04 at 22 °C	300 at 20 °C, pH 8 51 at 20 °C	Field crop boom sprayer	3600	100	1.3	XR 110–03	Normal	36	9	40, 20 20	2, 5	3.8
Trial 22	Winter barley	61	Germany	Fungicide	EC	297.5	2.79–2.98 at 20 °C	470 at 20 °C, pH 5	Field crop boom sprayer	7200	150	1.6	XR 110–04	Normal	72	10	20, 10, 10	2	1.7
Trial 23	Grapes	89	Italy	Fungicide	CS	297.5	2.79–2.98 at 20 °C	470 at 20 °C, pH 5	High crop trailed sprayer (broadcast air-assisted sprayer)	1440	502	14	ALBUZ AMT 012	Normal	6	7.8	18, 9, 9	3, 4.6, 6.9	2.8
Trial 24	Winter wheat	31	Germany	Fungicide	EC	344.26 312.2	3.82 at 20 °C, pH 7 3.04 at 22 °C	300 at 20 °C, pH 8 51 at 20 °C	Field crop sprayer	9360	114	2.1	Hypro F 110–03	Normal	72	12.2	40, 20 20	2	4.4
Trial 25	Winter wheat	31	Germany	Fungicide	EC	344.26 312.2	3.82 at 20 °C, pH 7 3.04 at 22 °C	300 at 20 °C, pH 8 51 at 20 °C	Field crop sprayer	9360	114	3	Lechler IDKN 120–03	DRN	72	12.6	20, 10, 10	2	3.5
Trial 26	Sugar beet	18	UK	Herbicide	SC	202.2	0.91	1770 at 25 °C, pH 7	Commercial ground boom sprayer	2400	181.3	3.5	NOZAL Flat fan / AFX 110–05 (Brown)	Normal	48	3.45	16, 8, 8	2	2.45
Trial 27	Sugar beet	18	UK	Herbicide	SC	202.2	0.91	1770 at 25 °C, pH 7	Commercial ground boom sprayer	2400	177.3	3.5	NOZAL Flat fan / AFX 110–05 (Brown)	Normal	48	3.33	16, 8, 8	2	2.49
Trial 28	Pre-emergence	NA (00)	UK	Herbicide	WG	214.3	1.8 at 25 °C	1040 at 20 °C, pH 6	Commercial ground boom sprayer	2400	205.8	1.3	NOZAL Flat fan / AFX 110–04	Normal	48	1.61	16, 8, 8	2	2.21

Table 1 (continued)

	Crop	BBCH stage	Country	Indication	Formulation type	Molecular weight of AI, g/mol	Log Pow of AI	Water solubility of AI, mg/L	Application method	Field size (m^2)	Water volume (L/ha)	Spray pressure (bar)	Nozzle type	Normal nozzles or DRN	Number of nozzles	Driving speed (km/h)	Replicates (total, adult, child)	Distance from zero line (m)	Average wind speed (m/s)
Trial 29	Pre-emergence	NA (00)	UK	Herbicide	WG	214.3	1.8 at 25 °C	1040 at 20 °C, pH 6	Commercial ground boom sprayer	2400	197.9	1.3	NOZAL Flat fan / AFX 110–04	Normal	48	1.47	16, 8, 8	2	2.86
Trial 30	Winter barley	26–28	UK	Herbicide	EC	221.03	− 0.82 at 20 °C, pH 7	24,300 at 20 °C, pH 7	Commercial ground boom sprayer	33,000	99	NA	Guardian air blue-03	Normal	48	NA	18, 9, 9	2, 5, 10	2.82
Trial 31	Winter wheat	26–28	UK	Herbicide	EC	221.03	− 0.82 at 20 °C, pH 7	24,300 at 20 °C, pH 7	Commercial ground boom sprayer	37,000	101	NA	Guardian air blue-03	Normal	48	NA	18, 9, 9	2, 5, 10	1.5
Trial 32	Winter barley	26–28	Ireland	Herbicide	SC	221.03	− 0.82 at 20 °C, pH 7	24,300 at 20 °C, pH 7	Commercial ground boom sprayer	35,000	200	NA	Hypro VP 110–035 brown/red nozzles	Normal	56	NA	18, 9, 9	2, 5, 10	1.8
Trial 33	Spring barley	27–28	France	Herbicide	SL	221.03	− 0.82 at 20 °C, pH 7	24,300 at 20 °C, pH 7	Commercial ground boom sprayer	88,000	157	NA	T-Jet 80–003 XR	Normal	72	NA	18, 9, 9	2, 5, 10	2.77
Trial 34	Spring barley	27–28	France	Herbicide	SL	221.03	− 0.82 at 20 °C, pH 7	24,300 at 20 °C, pH 7	Commercial ground boom sprayer	64,000	149	NA	Nozal ADX blue 120°	Normal	56	NA	18, 9, 9	2, 5, 10	2.1
Trial 35	Spring barley	26–28	Lithuania	Herbicide	EC	221.03	− 0.82 at 20 °C, pH 7	24,300 at 20 °C, pH 7	Commercial ground boom sprayer	20,200	203	NA	Lechler D-120–04	Normal	40	NA	18, 9, 9	2, 5, 10	2.8

DRN Drift-reducing nozzle (50%), *NA* Not available, Formulation types: *CS* Capsule suspension, *EC* Emulsifiable concentrate, *OD* Oil dispersion, *SC* Suspension concentrate, *SL* Soluble concentrate, *WG* Water dispersible granules sized mannequins. Inner dosimeters consisted of full-length underwear garments (long-sleeved vest and long johns) and a head sleeve. Outer dosimeters consisted of 100% cotton t-shirts and shorts in 26 trials and 100% t-shirt and 65% polyester/35% cotton shorts in 9 trials to represent a minimal clothing scenario for bystanders and residents. No further fabric/garment information was available in the collected data.

In total, 9 active ingredients (AIs) have been analysed from application of in-use dilutions of 6 different formulation types. The physico-chemical properties of analysed AIs (i.e. molecular weight, log P_{OW}, and solubility in water) for each trial are summarized in Table 1. The AIs used in this study are merely surrogate analytes that are measured on dosimeters. This follows the principle established by US EPA in 1996 in OPPTS 875.1000 (US EPA 1996).

2.3 Clothing (outer dosimeter)

Outer dosimeters consisted of 100% cotton t-shirts and shorts in 26 trials and 100% t-shirt, 65% polyester/35% cotton shorts in 9 trials covering the torso, half of upper arms, and half of thighs on adult mannequins, and torso, half or complete upper arms and half or complete thighs on children mannequins (one example is shown in Supplementary Fig. S2). The extent to which the arms and legs are covered by t-shirt and shorts in each study depends on the mannequin and the chosen clothing size. According to OECD guideline No. 9 (OECD 1997), t-shirts and shorts made of cotton or cotton/polyester mixtures were used in the studies.

2.4 Environmental conditions

All 32 studies (35 trials) captured wind speed, temperature, relative humidity, and rainfall measurements for the sampling periods. Wind speed was measured 2 m above ground. The overall range of wind speed across all trials was between 0.3 and 4.4 m/s; temperature was 2.2–32.2 °C; relative humidity was 32.3–96.6%. All trials had rainfall measurements available for sampling periods. Out of 32 studies, only 1 study had rainfall of 39.5 mm occurring during spray application.

2.5 Exposure reduction from minimal clothing

The residues of AIs in each trial were extracted from the garment samples using an appropriate extraction solvent, the extract then was analysed using LC–MS/MS system according to validated analytical method for each AI. The potential and actual dermal exposures on mannequins were measured as "mg/person", and then converted to "mL spray/person" by considering the concentration of the in-use spray dilution, i.e. mg/mL. Potential exposure in 35 trials was calculated as a sum of active ingredient residues on outer and inner dosimeters (i.e. t-shirt and shorts, the underwear (long sleeved t-shirt and long underwear trousers) and the head sleeve), which represents dermal exposure to a person with no clothing. Actual exposure considers active ingredient residues on inner dosimeters (i.e. long sleeved t-shirt and long underwear trousers and the head sleeve), which in turn represents dermal exposure to a person with light clothing. The reduction % was calculated as follows (Kuster et al. 2021):

$$Reduction\,\% = \frac{(\text{Potential exposure} - \text{Actual exposure})}{(\text{Potential exposure})} \times 100$$

Data were evaluated with R (R Core Team 2020). The following software extensions were used in R: readxl (Wickham et al. 2019a; b), to read in MS Excel files, tidyverse (Wickham et al. 2019a; b) for graphing and data wrangling, gridExtra (Baptiste 2017) for arranging multiple graphs within one figure, ggbeeswarm (Clarke and Scott 2017) for jittering individual data points to prevent or reduce overplotting, multcomp (Hothorn et al. 2008) for building models for multiple comparisons based on contrasts and ANOM (Pallmann and Hothorn 2016) for the analysis of means.

2.6 Statistical analyses

The impact of the various parameters on the reduction from light clothing was investigated by performing an analysis of covariance (ANCOVA) on a stratified dataset (Supplementary Table S2). This considered non-orchard and orchard crops, since the exploratory data analysis revealed a substantial effect of this factor which is not available for non-orchard crops. Data with DR nozzles (drift-reducing nozzles) and oil seed rape were excluded, as the observation number was rather small, comprising only a single study, and the reduction pattern is different (lower in children than in adults) to the other non-orchard crops (compare Fig. 2). For non-orchard crops, the null difference hypothesis is rejected at an alpha of 5% for the factors Child_or_Adult, Buffer, Spray_Pressure and Wind_Speed. For orchard crops, the null difference hypothesis is rejected at an alpha of 5% for the factors Crop, Buffer and leaf cover, while Child_or_Adult, Spray_Pressure and Wind_Speed are not statistically significantly different.

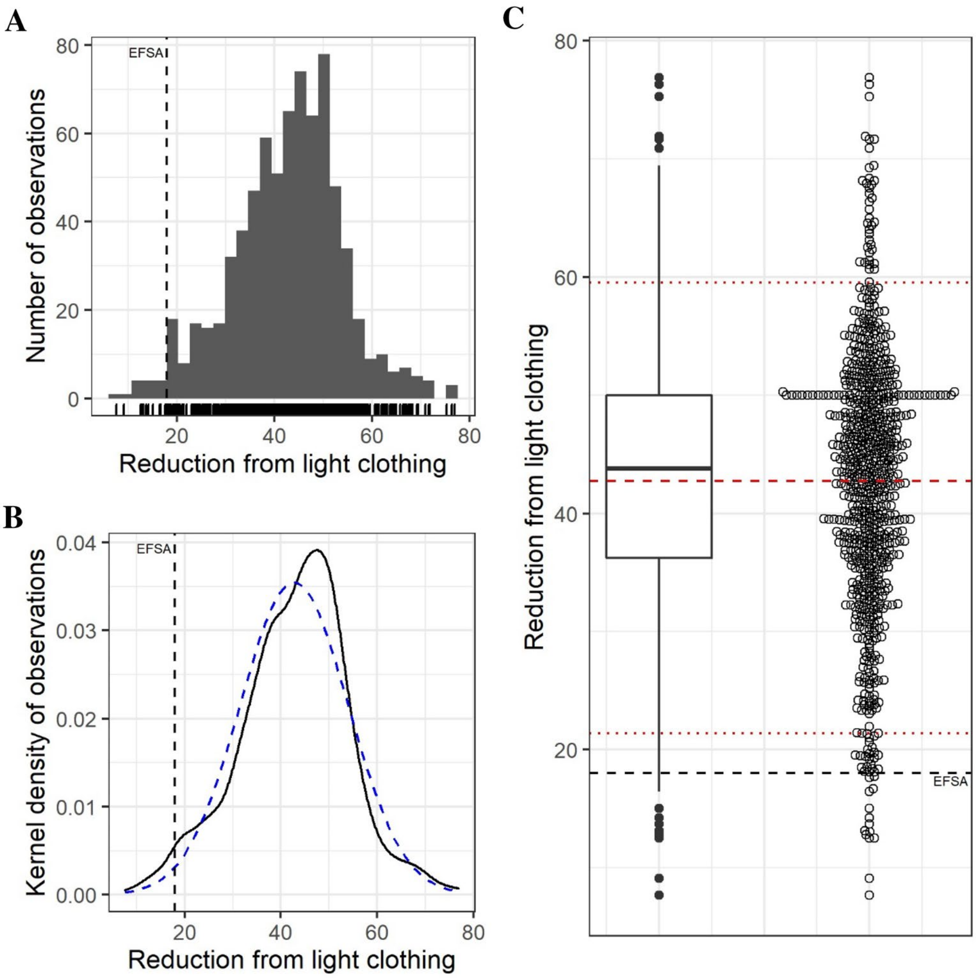

Fig. 1 Reduction factor distribution (complete dataset). The black dashed line indicates the EFSA (EFSA 2014; EFSA et al. 2022) reduction factor of 18%. **a** Histogram and rug plot, **b** Kernel density graph and corresponding normal distribution based on mean and standard deviation (dashed blue line), **c** Box plot showing 25th, 50th and 75th percentile (box) and minimum and maximum (whiskers). Values outside 1.5-times the interquartile range are depicted as single values. Further, individual values are depicted as a bee swarm plot. Red dashed line indicates the overall mean. Red dotted lines 5th and 95th percentiles

3 Results

3.1 Overview of all data points

Data from all 32 GLP studies (35 trials), with a total of 742 replicates for child and adult mannequins wearing 100% cotton t-shirts and shorts in 26 trials, and 100% t-shirts and 65% polyester/35% cotton shorts in 9 trials were analysed to address questions regarding the impact of light clothing on the reduction of exposure to spray drift from standard and drift-reducing (DR) nozzles. Figure 1 shows the distribution of all values in the dataset, and Table 2 shows the summary statistics. The percentage of reduction of exposure by light clothing (subsequently referred to as "reduction %") is greater than the EFSA value of 18% in most studies (depicted in Fig. 1 with a black dashed line), which was below the distribution's 5th percentile, with a mean reduction % of 42.7% and a median reduction % of 43.8% (Table 2). The value of 42.7% results in an AF of 57.3% (i.e. 0.573) in bystander/resident risk assessment. The mean reduction % for vineyard, especially early stage vineyard, was notably lower than the grand mean, which resulted in a lower grand mean than when these values were excluded (42.7% vs. 44.3% when vineyard values were excluded) (Table 2). The distribution approximated a normal distribution, generated based on mean value and standard deviation

Table 2 Summary statistics for the exposure reduction factors from ordinary light clothing – including all nozzles (standard and drift-reducing)

Statistic	Reduction (%)														
	All crops	High crops, all	Low crops, all	High crops, early stage, all	High crops, late stage, all	Vineyard, early stage	Vineyard, late stage	Pome fruit, early stage	Pome fruit, late stage	Pome fruit, all	Vineyard, all	Low crops, standard nozzles, all	Low crops, drift-reducing nozzles, all	All crops, excluding vineyard	All crops, excluding vineyard early stage
n	742	306	436	144	162	72	90	72	72	144	162	344	92	580	670
Mean	42.72	42.01	43.21	35.82	47.51	27.34	44.75	44.30	50.96	47.63	37.01	43.93	40.52	44.31	44.37
SD	11.26	12.03	10.68	11.56	9.53	7.74	8.26	7.94	9.93	9.56	11.81	9.04	15.08	10.58	10.29
Min	7.64	7.64	9.09	7.64	29.91	7.64	29.91	23.80	31.80	23.80	7.64	18.76	9.09	9.09	9.09
5th	21.39	20.17	23.60	18.19	34.10	17.16	32.64	33.21	37.10	35.19	18.35	29.42	13.97	25.85	26.57
10th	27.53	24.58	29.50	19.86	36.31	18.18	35.02	36.55	40.24	37.46	20.67	32.24	19.33	31.60	32.04
25th	36.21	35.38	36.65	26.63	40.51	21.29	38.11	39.56	44.44	42.38	28.26	37.59	28.10	37.99	38.03
Median	43.79	42.70	44.67	36.87	46.13	26.89	43.88	43.85	49.00	45.97	37.15	44.85	43.34	45.21	44.97
75th	50.00	48.71	50.00	43.96	52.62	33.46	50.94	47.23	55.10	51.75	44.82	50.15	50.00	50.23	50.26
90th	55.35	56.35	54.98	48.30	61.27	37.44	56.86	51.89	66.81	62.30	52.56	54.76	55.54	55.56	55.69
95th	59.53	62.25	58.12	51.88	64.63	38.87	58.95	55.47	69.34	68.15	56.87	57.39	62.50	61.15	61.10
Max	76.90	76.90	76.30	76.90	75.27	45.40	62.33	76.90	75.27	76.90	62.33	67.92	76.30	76.90	76.90

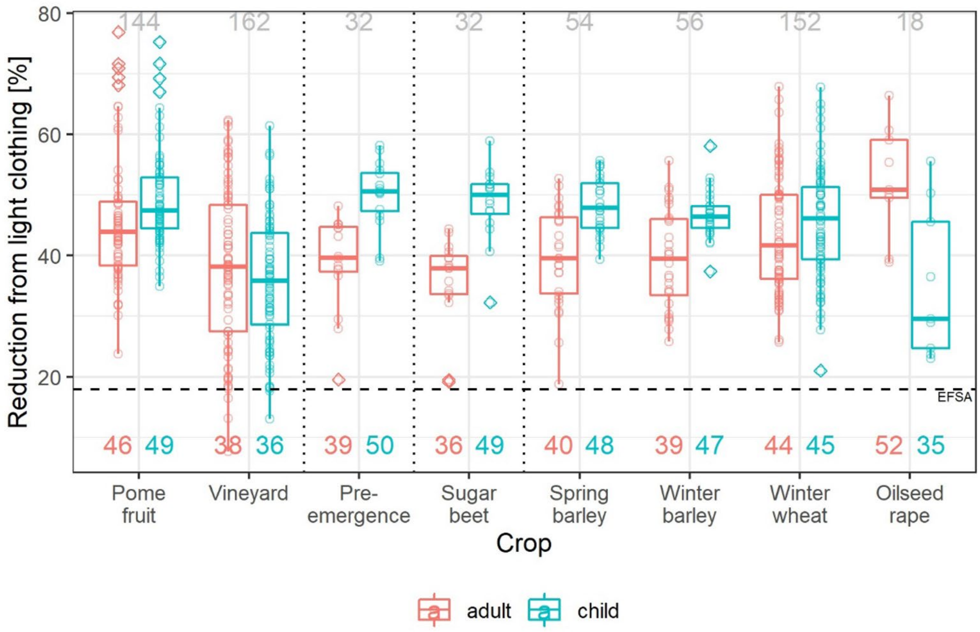

Fig. 2 Reduction from light clothing for various crops as box plots and stratified by child or adult-like mannequins. Outlier values (see boxplot description in the legend from Fig. 1) are indicated by a diamond shape. The observation number is given in grey at the top and rounded mean values at the bottom. The black dashed line indicates the EFSA (EFSA 2014; EFSA et al. 2022) reduction factor of 18%

(Fig. 1a). The 25th, 50th and 75th percentiles (box) and minimum and maximum values (whiskers) are listed Table 2 and depicted in the overall distribution in Fig. 1c. The spike at 50% in the beeswarm plot (Fig. 1c) showing individual values was driven by LOQs in one study.

3.2 Impact of crop type

The reduction % for child and adult mannequins according to the crop type is shown in Fig. 2. The reduction % was generally higher in children than in adult mannequins after spraying on different crop types. The exceptions to this are vineyard and oilseed rape; however, there is only a low number of observations for oilseed rape (18), and exposure after orchard spraying may be especially prone to bias due to the dependence of exposure on leaf cover (see below). The mean exposure reduction % for high crops is 42.01% and for low crops 43.21% (Table 2). Therefore, it can be considered that the provided protection for both crop groups is very similar.

3.3 Sources of variation

Supplementary Fig. S3 shows the impact of the leaf cover (according to whether early or late stage application) on the reduction % for child and adult mannequins after pome fruit and vineyard spraying. For both crop types, the larger leaf cover is linked to a higher reduction %. For example, for pome fruit spraying, the mean reduction % is increased from 42 to 50% for adults and from 47 to 52% for children. The effect of leaf coverage is more pronounced for vineyard spraying, where the mean reduction % increased from 27 to 47% and from 27 to 42% for adults and children, respectively. Of note, there are lower reduction % values in vineyard at early stage, which are from one study, where crop and mannequin row lengths were the same, i.e. spraying was started and stopped at locations coinciding with the first and last mannequin.

Another source of variation was wind speed; however, no clear correlation was determined from the data (not shown). It is also unclear whether there was a substantial buffer effect on the reduction % in non-orchard and orchard crops, whereby interaction effects make a more refined statistical analysis challenging and prone to bias.

The effect of DR nozzles and the spray pressure on the reduction % in oilseed rape and winter wheat is shown Supplementary Fig. S4. DR nozzles decrease the reduction % for adult and child mannequins after spraying on oilseed rape (lower panels). There is also a lower reduction % by DR nozzles in winter wheat (top panels); however, the effect may be confounded by spray pressure, which is different in the comparisons. When compared at the same spray pressure (red bars), there is little impact of the DR nozzles on the reduction % in winter wheat. For winter wheat, a higher spray pressure decreases the reduction % by both standard

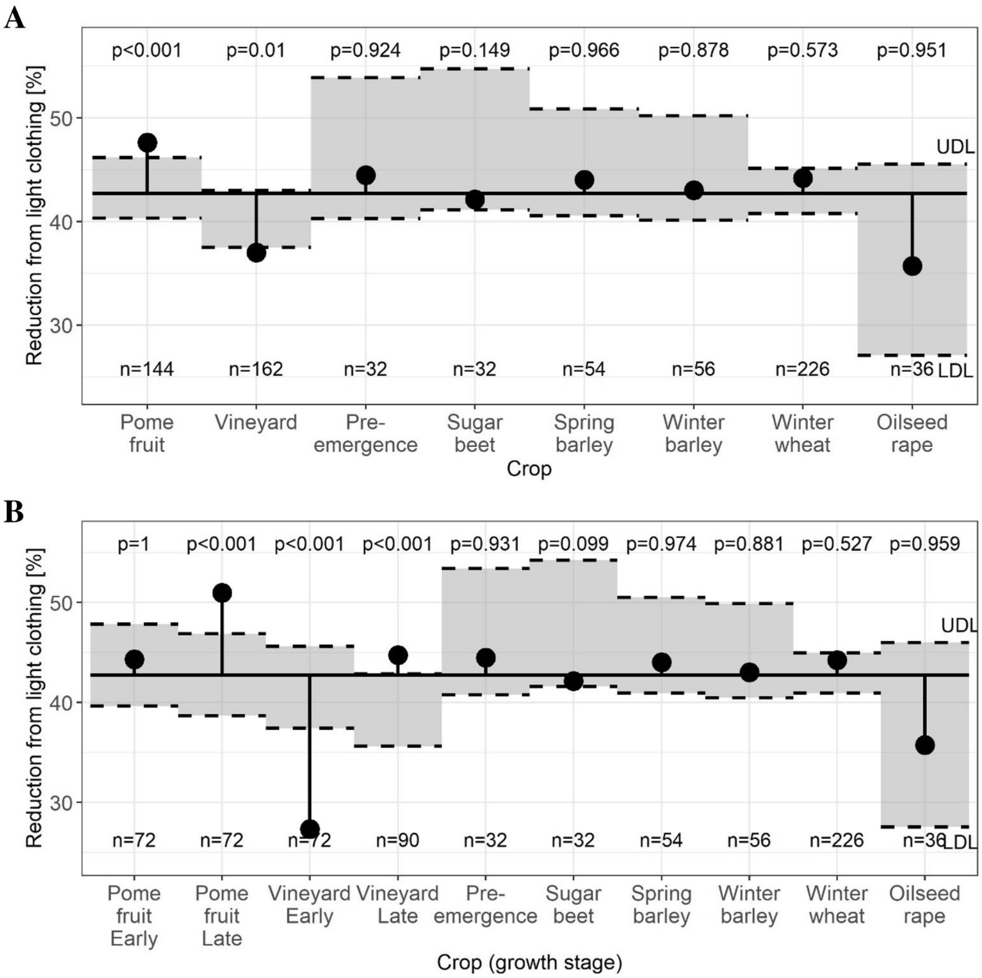

Fig. 3 Analysis of means, i.e. a multiple contrast test involving comparisons of each group vs. the grand mean. Points outside the grey decision area, which is based on the number of observations, are statistically significantly different. **a** Considering the effect of crop and interaction of child *vs.* adult and **b** growth stage for the orchard crops

("no DR nozzles") and DR nozzles. The mean exposure reduction % for low crop standard nozzles is 43.93% and for DR nozzles 40.52% (Table 2). However, when looking at 2 of 3 concurrent trial pairs in the dataset, the impact from DR nozzles could be observed (as shown also in Supplementary Fig. S4). Due to different crops, equipment used, water volume, pressure, etc., the driver of reduced exposure reduction % could not be determined.

3.4 Analysis of means

Considering the effect of crop and interaction of child vs. adult in a linear model, the individual mean differences from the grand mean can be investigated (Fig. 3). This can be facilitated by an analysis of means (Ott 1983), which is a multiple contrast test that relates to technical control charts used in process control. Using the R package ANOM (Pallmann and Hothorn 2016), the pome fruit reduction % mean is statistically significantly higher, while the vineyard mean is significantly lower than the grand mean (Fig. 3a). All other means are comparable, hence, the reduction % can be considered to be similar between crops with the exception of orchards (pome fruit and vineyards). Figure 3b shows the impact of the growth stage on the means reduction % for orchard and vineyard crops. This indicates that orchard crops have a comparable or higher mean than the grand mean, with the exception of vineyard early stage, which was lower than the grand mean.

3.5 Analysis of covariance

The impact of the various parameters on the reduction from light clothing was analysed using ANCOVA on a stratified dataset. The results of the ANCOVA are shown in Supplementary Table S2 and generally support the conclusions from the comparisons described above. This is in accordance

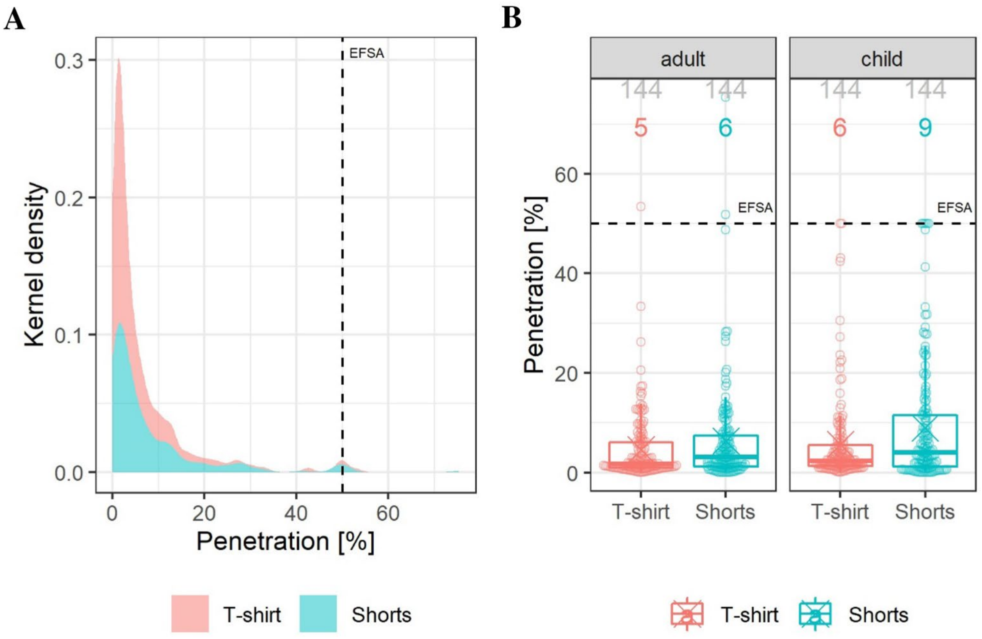

Fig. 4 Penetration through light clothing. The current default EFSA assumption is 50%, which is indicated in the graph as a dashed line. **a** Kernel density/distribution of the full dataset. **b** Boxplots, individual values and mean (multiplication sign), and stratified by adult and child. Observation number is given in grey at the top and rounded mean values below

with the analysis of means, such that the crops are compatible and have a similar grand mean.

Using 90% confidence intervals on the slopes of the linear model excluding vineyard, pomefruit and oilseed, the factor child increased the reduction % by 2.4–5.9 percentage points, spray pressure decreased the reduction % by 0.96–3.5 percentage points and wind speed decreased the reduction % by 4.8–2.8 percentage points for every unit increase in this model, while buffer is compatible with a slope of 0. Using 90% confidence intervals on the slopes of the linear model considering only vineyard and pome fruit, buffer decreased the reduction % by 0.002–0.46 percentage points, spray pressure increased the reduction % by 0.28–0.57 percentage points, which may be considered to be negligible effects. Wind speed increased reduction % by 1.6–4 percentage points while a late growth stage increased the reduction % by 11–15 percentage points in this model.

3.6 Penetration through light clothing

The dataset also allows an assessment of how much protection is gained from light clothing by investigating the amount penetrating from the outer to the inner dosimeter. In studies where inner and outer dosimeters made of 100% cotton were sectioned and closely matched, i.e. torso and upper arms with t-shirt and waist and thighs with shorts, it is possible to determine the penetration of spray droplets through the outer dosimeter (clothing). In the dataset, 16 studies comprising 288 replicates are considered where the dosimeters were sectioned to be matched. These studies were conducted in high crops (pome fruit and vineyard) covering early and late stages. Figure 4a shows the distribution of the penetration data, which is very skewed to values much lower than 10% and is close to log-normal (not shown). Figure 4b shows the % penetration through t-shirts and shorts worn by adult and child mannequins (the statistics summary is shown in Supplementary Table S3; individual penetration values for t-shirts and shorts are shown in Supplementary Table S4). The mean penetration through t-shirts was 5.12% and through shorts 7.65% for both adult and child mannequins. Combining data from t-shirt and shorts, the mean penetration is 6.39%, which leads to a protection by light clothing of 93.61%. Notably, the median penetration was much lower, i.e. 2.04% for t-shirts and 3.48% for shorts.

4 Discussion

Data from recent bystander field studies containing 35 trials with 742 replicates were used to derive a refined AF for a more precise dermal exposure to direct spray drift, and thus refine product specific risk assessments. The mean and 25th percentile reduction % in children and adults for all crops and standard and DR nozzles were 42.7% and

36.2%, resulting in AF of 0.573 and 0.638, respectively, in bystander/resident risk assessment. Generally, for most crops the reduction % from light clothing is marginally higher in children than in adults. Sources of variation were investigated, which indicated that reduction % could be impacted by several conditions: crop type (also whether it was non-orchard or orchard), leaf coverage, buffer, spray pressure, and the type of nozzle. Those were all evaluated but, with one exception, the reduction % was similar between the crops. This indicates that a single value covering all crops could be derived. The exception to this was for early vineyard scenarios (the reduction % was lower (27%) than late stage (42–47%)), which could be considered individually to avoid unnecessary conservatism for the other scenarios.

The AF of 0.573 and 0.638 for mean and 25th percentile, respectively, were lower than the currently applied AF of 0.82 recommended by EFSA guidance (EFSA 2014) and can be considered to be a refined and conservative values based on measured data. As mentioned, the proposed default 50% penetration in the EUROPOEM 1996 report was merely a preliminary estimation derived from operator exposure data, leading to the AF of 0.82 in EFSA guidance. However, our bystander exposure data have allowed to derive an exposure-specific (i.e. very brief exposure to spray drift in bystander exposure instead of splashes, spray drift over the workday and contact with contaminated surfaces in operator exposure) AF of 0.573 and 0.638 for mean and 25th percentile, respectively. As a result, the impact on spray drift exposure estimation by not changing any other parameter would be a more realistic outcome, reducing the estimated exposure by factor 1.43 and 1.29 for mean and 25th percentile, respectively, as compared to the current approach by EFSA 2014 and 2022.

The studies were conducted under representative label recommendations and field application conditions and represent conservative measurements. Because the trials depicted a highly unlikely scenario with respect to the close proximity of mannequins to the source of application. For example, the mannequins were positioned facing the treated area at various distances downwind from the zero position, with prevailing wind direction at approximately 90° angle to the orientation of the rows and/or direction of spray. In addition, the spray drift was determined at a static location directly adjacent to the field. It is extremely unlikely that any person, be it bystander or resident, would spend an extended period of time in a direct spray drift without being aware of the spraying event taking place (EFSA et al. 2022). The total number of passes in the studies were 2–30 in different crops, which corresponds to exposure duration of 2 min to more than 1 hour. By contrast, bystander exposure duration while walking, running or cycling past a simultaneously sprayed field would be very short.

According to EUROPOEM 1996, consideration should be given to the ambient conditions and especially air movements, which could influence the spray drift direction and consequently bystander exposure. The wind speed range in the 35 trials was between 0.3 and 4.4 m/s (i.e. 1.08 and 15.84 km/h). This range covers “Force 0 to Force 4” according to the UK spray guide (DEFRA 2006) or “Calm to Moderate” according to the FAO (FAO 2001). Force 4 (9.6–14.5 km/h) is equivalent to 2.667–4.028 m/s, which was considered in the current analysis since 13 studies were conducted under wind speeds of ≥ 2.7 m/s. Likewise, Force 3 (6.5–9. km/h), equivalent to 1.806–2.667 m/s was also considered in 10 studies, during which wind speeds were within this range. Based on those results, the drift deposition on the mannequins from this study can be considered as very conservative. Climate conditions could be considered with a probabilistic approach or by considering different climate scenarios in risk assessment when a deterministic approach is used. Additionally, the current EU risk assessment takes a deterministic approach with repeated subsequent exposures to spray drift and a duration of 90 days (if the AOEL is based on a 90-day study) (Kluxen et al. 2021).

According to the EFSA guidance (EFSA 2014), the reduction from light clothing is determined as follows:

$$\begin{aligned}&\%\,\text{Reduction from light clothing}\\&=36\%\text{ of body covered}\times 50\%\text{ protection}=18\%\end{aligned}$$

In order to validate the penetration and determine a reduction factor from light clothing, a more detailed refinement of covered body areas was considered. The body surface areas according to EFSA (2014; 2022) are not sufficiently stratified for this purpose; therefore, as a reference for a more detailed body area calculation, data from US EPA Exposure Factors Handbook were used (US EPA 2011). Adult male data were used since they contain more detailed separation of body parts compared to adult females. As shown in Supplementary Fig. S2, for an adult, areas covered by a t-shirt and shorts include the torso, half of the upper arm, and half of the thigh. According to US EPA (2011), the mean surface area covered for an adult male is 54% of the whole body. For a child (2 yrs. old, male and female), the mean covered surface area is 64% when the t-shirt fully covers the upper arm and the shorts fully cover the thigh. If the t-shirt covers half of the upper arm and the shorts cover half of the thigh, the mean covered surface area is 52%. For example, by refining the covered body surface area (52%) and including the protection from light clothing (93.61%–derived from the analysis of the current data set), the reduction from light clothing is as follows:

$$\begin{aligned}&\%\text{Reduction from light clothing}\\&=52\%\text{ of body covered}\times 93.61\%\text{ protection}=48.68\%\end{aligned}$$

This value is in agreement with mean reduction factor derived from the dataset considered in this work (which was 42.7%).

EFSA (2014) assumes a 50% penetration through light clothing; however, this value is likely to be much lower, i.e. 2–20% (EUROPOEM 1996). The current evaluation is in accordance with the EUROPOEM report, with a mean and 75th percentile penetration of 6.39% and 7.38% through t-shirt and shorts, resulting in a protection by light cotton clothing of 93.61% and 92.62%, respectively. Additionally, further consideration could be given to the loading in µg/specimen and the corresponding % penetration, and further research could be conducted (EUROPOEM 1996). Interestingly, the available data show an inverse relationship between loading in µg/specimen to % penetration (not shown), which is similar to the inverse relationship we see in other areas, e.g., a higher loading dose along with a lower relative absorption in dermal absorption studies (Buist et al. 2017; Kluxen et al. 2022).

The current data address the penetration through and protection provided by cotton and cotton/polyester clothing, and further consideration could be given for other types of clothing materials (e.g. synthetic or semi-synthetic fabrics such as acrylic, nylon, rayon etc.) with a potentially higher penetration factor than cotton, cotton/polyester or wool clothing (Saleh et al. 1998). Furthermore, due to a lack of sufficient data at present, the exposure reduction due to clothing does not address different seasonal clothing in different climates and weather conditions (e.g. March in Northern Europe or July in Southern Europe), nor the activity in which the bystander or resident might be engaged in (EUROPOEM 1996). Further consideration should be given that in colder climates the clothing could be more substantial than t-shirt and shorts, e.g. long-sleeved shirt or jacket and long trousers, and a relevant protection factor could be addressed accordingly. However, if bystanders are wearing full clothing, the clothing would be capable of absorbing the contaminants to some extent and so reduce their likely level of actual dermal exposure (EUROPOEM 2002). Additionally, in warmer months of the year or warmer climates, bystanders/residents may be wearing less clothing than t-shirt and shorts, e.g., bathing suits. Consequently, further consideration should be given for the covered body surface area as well as the impact of the clothing material on the exposure reduction factor.

In “spray drift”, “surface deposits”, and “entry into treated crop” scenarios (EFSA 2014), a certain amount of exposure may be reduced due to ordinary clothing. However, the assumptions and protection provided by light everyday clothing is not addressed consistently in the risk assessment process. For the abovementioned exposure scenarios, different assumptions for clothing are applied: spray drift scenario assumes only the trunk is covered, and dermal exposure incorporates “transfer coefficient” (TC) values due to surface deposits, taking into account a minimal protection from clothing, however, no further clarification of the covered body parts is available. And during the entry into treated crops, it is assumed that lower legs and arms are uncovered. Considering the fact that the EU risk assessment assumes a single person is being exposed via 4 different pathways, harmonization of the provided clothing and protection should be considered accordingly.

5 Conclusion

In response to the recommendation by EFSA (2014) to generate data in order to reflect more realistic scenarios for the derivation of AFs for direct spray drift exposure, CropLife Europe (CLE) member companies conducted 32 field studies under representative label recommendations and field application conditions. The evaluated data enabled the derivation of a refined AF for a more precise estimation of dermal exposure to direct spray drift. The reduction % may be impacted by several conditions. However, the reduction % could be similar between crops and therefore, a single AF value was considered suitable for all crops. One exception was the early stage vineyard scenarios (the reduction % was lower (27%) than at late stage (42–47%)). However, this scenario could be looked at individually in order to avoid unnecessary conservatism for the other scenarios. In summary, our evaluation of 32 scenario-specific field studies suggests that a more realistic, exposure scenario-d relevant AF value should be applied for bystander/resident risk assessment.

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Data availability Data available on request.

Declarations

Competing interests Edgars Felkers, Christian J. Kuster, Sarah Adham are members of the CLE Occupational and Bystander Exposure expert team; Edgars Felkers and Felix M. Kluxen are members of the CLE Dermal Absorption expert team. These authors provided funding for this study and designed and executed the study and have sole responsibility for the writing and content of the manuscript. Nicola Hewitt is a scientific consultant. None of the authors have a conflict of interest.

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