GUIDANCE OF EFSA

Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products[1]

European Food Safety Authority[2,3]

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ABSTRACT

Regulation (EC) No 1107/2009 ensures that the residues of plant protection products (PPPs), consequent to application consistent with good plant protection practice and having regard to realistic conditions of use, shall not have any harmful effects on human health. In 2010, the EFSA Panel on Plant Protection Products and their Residues (PPR) prepared a Scientific Opinion on "Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Residents and Bystanders", which highlighted some inconsistencies between the approaches adopted by regulatory authorities. Therefore, the PPR Panel proposed a number of changes to those practices in use (e.g. routine risk assessment for individual PPPs should continue to use deterministic methods, and a tiered approach to exposure assessment remains appropriate; there is a need to introduce an acute risk assessment for operators, workers and bystanders where PPPs are acutely toxic; for acute risk assessments, exposure estimates should normally be based on 95th percentiles of relevant datasets, whereas, for longer term risk assessments, the starting point should be a 75th percentile). To prepare a Guidance Document, an *ad hoc* working group was established to revise all available data and procedures to perform the operator, worker, resident and bystander risk assessment. In addition to the data reported in the PPR opinion, further data were made available to the working group which were analysed and considered. The opinion also identifies those scenarios for which exposure estimates are least satisfactory, and makes recommendations for further research that would reduce current uncertainties. An exposure calculation spreadsheet, reflecting the Guidance content, is annexed to this Guidance Document, to support stakeholders in performing the assessment of exposure and risk.

KEY WORDS

exposure, operator, worker, bystander, resident, plant protection products, estimation, guidance, calculator

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SUMMARY

Based on the "Scientific Opinion on Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Residents and bystanders" prepared by the EFSA PPR Panel in 2010 and on the subsequent public consultation, EFSA was asked to proceed with the preparation of a Guidance Document on the topic, in accordance with Article 31 of Regulation (EC) No 178/2002.

The Guidance is designed to assist risk assessors and notifiers/applicants when quantifying potential non-dietary, systemic exposures as part of regulatory risk assessment for plant protection products (PPPs). It is based on an initial draft that was presented as part of the EFSA PPR Panel opinion (EFSA PPR Panel, 2010), followed by further developments and then revision after public consultation held in 2014 (EFSA Technical Report "Outcome of the Public Consultation on the draft EFSA Guidance Document on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products").

Risk assessments must be carried out for all scenarios of exposure of operators, workers, residents and bystanders that can be expected to occur as a consequence of the proposed uses of a PPP. Most exposure scenarios will fall into a category for which a standardised first tier exposure assessment can be applied as described in the Guidance. For scenarios that are not covered by these standardised methods, the risk assessor will need to follow an *ad hoc* approach that is judged to be the most appropriate. An *ad hoc*, higher tier, exposure assessment may also be used for exposure scenarios that are covered by a standardised first tier method. However, this should be done only if there are good grounds for concluding that the *ad hoc* method will provide a more reliable and realistic estimate of exposures arising from the proposed good plant protection practice than the standard method. The Guidance also identifies those scenarios for which exposure estimates are least satisfactory, and makes recommendations for further research that would reduce current uncertainties. An exposure calculation spreadsheet, reflecting the Guidance content, is annexed to this Guidance Document, to support stakeholders in performing the assessment of exposure and risk.

The Guidance should hereafter be reviewed periodically, as and when relevant new data become available, and, if appropriate, should be amended or revised.

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BACKGROUND AS PROVIDED BY THE COMMISSION

EFSA issued in 2010 a "Scientific Opinion on Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Residents and bystanders". This opinion raised a number of questions for risk managers, which had to be addressed before EFSA could finalise the Guidance Document.

A working group of risk managers was set up and a meeting took place in Brussels on 11 May 2011 to discuss about the specific questions raised by EFSA. The outcomes of this meeting have been presented at the meeting of the Standing Committee on the Food Chain and Animal Health held on 16–17 June 2011 and have been communicated to EFSA (Pesticides Unit).

Based on the response to the opinion, EFSA is asked, in accordance with Article 31 of Regulation (EC) No 178/2002, to proceed with the preparation of a Guidance Document on the Pesticide Exposure Assessment for Workers, Operators, Residents and Bystanders.

TERMS OF REFERENCE

EFSA is asked to proceed with the preparation of an EFSA Guidance on pesticide exposure assessment for operators, workers, bystanders, and residents for the use in regulatory risk assessment of plant protection products.

In particular this will include:

- A quality assessment of the databases made available to EFSA for the purpose of this mandate on pesticide exposure assessment for operators, workers, residents and bystanders.
- The derivation of regulatory percentiles from the most appropriate datasets of the above databases for each of the commonly encountered exposure scenarios
- The preparation of an exposure calculator spreadsheet
- The finalisation of the draft Guidance proposed in the scientific opinion of the EFSA PPR Panel considering the responses received from DG SANCO

The Commission will be consulted on the technical practicalities of the spreadsheet.

ASSESSMENT

1. Introduction

This Guidance is designed to assist risk assessors and notifiers/applicants when quantifying potential non-dietary, systemic exposures as part of regulatory risk assessment for plant protection products (PPPs). It is based on an initial draft, presented as part of a published opinion of the EFSA PPR Panel (EFSA PPR Panel, 2010), followed by further developments and then revision after public consultation held in 2014 (EFSA Technical Report "Outcome of the Public Consultation on the draft EFSA Guidance Document on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products").

An *ad hoc* EFSA working group (hereafter "WoG") was established to prepare a Guidance Document (GD) and the related exposure calculator.

Guidance does not represent a legally binding tool. However, any departure from the procedures described should be justified by sound scientific arguments when a proposal for risk assessment is submitted.

The aim of exposure assessment in this context is to consider realistic and high exposure scenarios arising from the proposed Good Agricultural Practice for non-dietary systemic exposure that can be compared with appropriate toxicological reference values.

Risk assessments must be carried out for all scenarios of exposure of operators, workers, residents and bystanders that can be expected to occur as a consequence of the proposed uses of a PPP. Most exposure scenarios will fall into a category for which a standardised first tier exposure assessment can be applied as described in this Guidance. For scenarios that are not covered by these standardised methods, the risk assessor will need to follow an *ad hoc* approach that is judged to be the most appropriate.

An *ad hoc*, higher tier, exposure assessment may also be used for exposure scenarios that are covered by a standardised first tier method. However, this should be done only if there are good grounds for concluding that the *ad hoc* method will provide a more reliable and realistic estimate of exposures arising from the proposed good plant protection practice than the standard method. This conclusion must take into account the quality and quantity of data underpinning the *ad hoc* assessment compared with the standard method, and also the closeness with which the data relate to the exposure scenario under consideration. Where a non-standardised higher tier exposure assessment is adopted, the justification should be clearly documented.

2. Background data

Currently, there is no harmonised approach to pesticide exposure assessment for operators, workers, residents and bystanders. For the evaluation of active substances and PPPs under Council Directive 91/414/EEC[4] and Regulation 1107/2009[5], models developed in the UK or Germany are normally used to assess the potential exposures of operators, but these models give somewhat different estimates for the same scenario. Worker exposures may as well be estimated using different models, as no standardised methods are available to assess the exposures of residents and bystanders, and different Member States follow different approaches.

The activity of the WoG started with the assessment of the available databases to be considered for the preparation of the Guidance (see table 1).

Basic principles of the present Guidance and the annexed exposure calculator (see Appendix E) are the transparency of data, the traceability of information and the reproducibility of the outcomes. Therefore, it was decided to consider only databases of raw data or peer-reviewed publications that could be accessed by the WoG and, if requested, by third parties, in accordance with the Aarhus Convention. In this case, the normal procedures include contacting the owner of the documents before any release is made.

Furthermore, the activity is aimed at standardising exposure assessments better than at present, and, at the same time, addressing some of the shortcomings in the current methodology that have been identified. The Guidance can subsequently be reviewed and, if appropriate, amended or revised as and when new data become available (e.g. the EU funded BROWSE Project—EU 7th Framework Programme "Bystanders, Residents, Operators and Workers Exposure models for plant protection products" is expected to report revised or new exposure models). Because of the limitations of data currently available, the deterministic methods in routine risk assessment for individual PPPs and a tiered approach to exposure assessment remain appropriate. In addition, there is a strong argument that the method of risk assessment should be refined for pesticides that may present a risk of detrimental effects after one day of exposure.

Table 1: Overview of available database and models

Exposed category	Database/model	Availability of supporting data Yes	No	Reference
Operator (field)	German model	x		Lundehn et al. (1992)
Operator (field)	UK POEM	x		UK MAFF (1986) and the Predictive Operator Exposure Model (POEM—UK MAFF, 1992)
Operator (field)	Agricultural operator exposure model (AOEM)	x		Großkopf C. (2013), A new model for the prediction of agricultural operator exposure during professional application of plant protection products in outdoor crops Available at http://www.bfr.bund.de/cm/350/joint-development-of-a-new-agricultural-operator-exposure-model.pdf
Operator (field)	EUROPOEM II	x		EUROPOEM II (2002)
Operator (field)	PHED	x		PHED (1992)
Operator (field)	TNsG Biocides		x	TNsG (2008) TNsG (2002) Human exposure to Biocidal Products—Guidance on exposure estimation

4 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–290.

5 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EC and 91/414/EEC. OJ L 309, 24.10.2009, p. 1–50.

Exposed category	Database/model	Availability of supporting data Yes	No	Reference
				(June 2002) TNsG (2007) Human exposure to Biocidal Products (June 2007)
Amateur	ConsExpo		x	Bremmer et al (2006) ConsExpo 4.0, Consumer Exposure and Uptake Models http://www.rivm.nl/en/Library/Scientific/Models/Download_page_for_ConsExpo_software
Amateur	French data		x	UPJ (Union des Entreprises pour La Protection des Jardins), unpublished
Operator (greenhouse)	Industrieverband Agrar (IVA)—Germany	x		Mich (1996)
Operator (greenhouse)	Southern Europe		x	Unpublished, ECPA model
Operator (greenhouse)	Dutch		x	Unpublished, Dutch authorities, data open literature (1992)
Operator (seed treatment)	SeedTropex		x	Unpublished, UK—FR, Industry data (1996)
Worker	EUROPOEM II	x		van Hemmen et al. (2002)
Worker	German	x		Krebs et al (2000)
Worker (fork lift driver, sowing)	SeedTropex		x	Unpublished, UK—FR, Industry data (1996)
Worker	Transfer coefficient		x	US EPA (2000 and 2011)
Residents and bystanders	EUROPOEM II	x		van Hemmen et al. (2002)
Residents and bystanders	BREAM (Resident and Bystander Exposure Assessment Model)	x [(a)]		Silsoe Spray Application Unit, The Arable Group, http://randd.defra.gov.uk/Document.aspx?Document=11392_PS2005Finalreportforpublication.pdf, Butler Ellis et al. (2010a, b), Butler Ellis and Miller (2010), Glass et al. (2010, 2012), Kennedy et al. (2012)
Residents and bystanders	ConsExpo		x	Bremmer et al (2006) ConsExpo 4.0, Consumer Exposure and Uptake Models. http://www.rivm.nl/en/Library/Scientific/Models/Download_page_for_ConsExpo_software
Residents and bystanders	Lloyd and Bell 1983 and 1987 (spray drift values)	x [(a)]		Lloyd and Bell (1983), Lloyd et al. (1987)
Residents and bystanders	CRD 2008	x		Available online: http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/enforcement/resident-and-bystander-exposure-to-pesticides
Residents and bystanders	California EPA	x [(a)]		Californian Department of Pesticide regulation, Toxic Air Contaminant Program Monitoring Reports http://www.cdpr.ca.gov/docs/emon/pubs/tac/tacstdys.htm
Residents and bystanders	Ganzelmeier spray drift data	x [(a)]		Ganzelmeier and Rautmann (1995); Rautmann et al. (2001)

Exposed category	Database/model	Availability of supporting data Yes	No	Reference
Residents and bystanders	BfR 2008	x [(a)]		Martin et al. (2008)

(a): Public data only.

3. Definitions of exposed groups

For the purpose of this Guidance, the following definitions have been adopted:

- **Operators** are: persons who are involved in activities relating to the application of a PPP; such activities include mixing/loading the product into the application machinery, operation of the application machinery, repair of the application machinery whilst it contains the PPP and emptying/cleaning the machinery/containers after use. Operators may be either professionals (e.g. farmers or contract applicators engaged in commercial crop production) or amateur users (e.g. home garden users; it is noted that this Guidance does not include an assessment of this scenario).
- **Workers** are: persons who, as part of their employment, enter an area that has been treated previously with a PPP or who handle a crop that has been treated with a PPP.
- **Bystanders** are: persons who could be located within or directly adjacent to the area where PPP application or treatment is in process or has recently been completed; whose presence is quite incidental and unrelated to work involving PPPs, but whose position might lead them to be exposed during a short period of time (acute exposure); and who take no action to avoid or control exposure.
- **Residents** are: persons who live, work or attend school or any other institution adjacent to an area that is or has been treated with a PPP; whose presence is quite incidental and unrelated to work involving PPPs but whose position might lead them to be exposed; who take no action to avoid or control exposure; and who might be in the location for up to 24 hours per day (longer term exposure).

Operators, workers, residents and bystanders may be exposed to pesticides either directly through contact with spray drift (via dermal or inhalation routes) or indirectly through contact with drift deposits (dermal or ingestion) or vapour drift arising from volatilisation of deposits. Exposure is expected to decline over time from the initial value at, or close to, the time of application.

Therefore, the total exposure from application of an active substance results from different exposure routes. However, for non-dietary exposure pathways, other than dermal or inhalation, in most cases few data are available to provide quantification of their impact on the overall exposure assessment. Some are unlikely to contribute significantly to the overall body burden of the pesticide, except for the hand or object to mouth transfer for toddlers. The Guidance is expected to assess the major exposure pathways that also cover minor exposure pathways. Nevertheless, the WoG recommends that further research be carried out to perform a more representative exposure assessment.

4. Overall approach

4.1. Step 1: identification of risk assessments that are required

The first step is to establish the risk assessments that will be required. This will depend upon who can be expected to incur exposure as a consequence of the intended use of the PPP (operators, workers, residents, bystanders), and also on whether the PPP has potential for systemic toxicity from exposure during a single day. The answer to this second question will be determined as part of the toxicological evaluation (it will also normally be relevant as to whether an acute dietary risk assessment is needed).

Depending on the exposed groups and potential for toxicity from acute exposures, risk assessments will be required as set out in Table 2.

For PPPs that are acutely toxic and where an appropriate reference value has been set, realistic upper estimates of exposure in a single day for operators, workers, residents and bystanders should be considered. The exposure assessment for bystanders should cover the realistic upper estimate of exposure that a resident could reasonably be expected to incur in a single day. Therefore, any risk to residents from exposures that can take place within a single day, and may produce effects, would be covered by the risk assessment for bystanders, and there would be no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 2: Risk assessments required (adapted from EFSA PPR Panel, 2010)

Exposed group	**Risk assessments that may be required**	
	PPPs with no potential acute systemic toxicity	**PPPs with potential for acute systemic toxicity**
Operators	**L**	**A, L**
Workers	**L**	**A [(a)], L**
Residents	**L**	**L (A covered by bystander)**
Bystanders	**L (covered by residents)**	**A**

(a): An acute assessment is in principle needed but in the current Guidance insufficient data are available to perform it.
A, acute risk assessment; L, longer term risk assessment; PPP, plant protection product.

The exposure assessments have to be compared with the relevant reference values.

4.2. Step 2: use standardised first tier methods of exposure assessment where available

For each risk assessment that is deemed necessary, potential daily exposures should be assessed using standardised methods where available. These methods have been defined for the most commonly occurring exposure scenarios, which are specified in terms of:

- The category of individual exposed—operator, worker, resident or bystander.
- The type of the PPP—for example whether it is formulated as a solid or a liquid.
- The operations that will be carried out with the PPP and the equipment that will be used—for example mixing and loading, application by tractor-mounted equipment, outdoor application with hand-held application equipment.
- The intended uses.

In some cases it may be necessary to combine exposures from two or more activities to obtain a figure for the total potential daily exposure—for example, an operator might have components of exposure, during mixing and loading, spraying or in some cases when acting as a worker in the same day. However, in the case of different activities performed in the same working day (e.g. an operator doing mixing/loading, application and cleaning and also re-entering a treated field) it is justified to consider the exposure resulting from operator activities over a single day representing the worst-case scenario.

In the case of professional operators and workers, it may be determined that it is necessary to reduce exposure effectively through the use of personal protective equipment (PPE). If so, the exposure of these groups should, where possible, be assessed both with and without the proposed PPE. The multiplying factors by which PPE can be assumed to reduce exposures are set out in Table 7. If valid measured values are available, they should be used.

4.3. Step 3: use appropriate *ad hoc* methods where standardised first tier methods of exposure assessment are not available or where appropriate *ad hoc* methods are more realistic

Where no standardised first tier method of exposure assessment is available, it will be necessary to apply an appropriate *ad hoc* method. Where *ad hoc* methods are more realistic, they should be applied. This will normally be based on higher tier field studies with the necessary number of subjects (e.g. as required by OECD (1997)).

For risk assessments in relation to acute exposures (i.e. those that could occur in a single day), exposure estimates should, as a default, be derived as the higher of: (a) the 95th percentile of the distribution of measurements in the sample (the level of exposure an individual in the population can experience over a single day); or (b) a statistical estimate of the 95th percentile for the theoretical population of measurements from which the sample was derived, under the assumption that this population has a log-normal distribution (EFSA PPR Panel, 2010).

For risk assessments in relation to longer term exposures, exposures should, as a default, be derived as the higher of: (a) the 75th percentile of the distribution of measurements in the sample (the level of exposure an individual in the population can experience repeatedly each day over a season); or (b) a statistical estimate of the 75th percentile for the theoretical population of measurements from which the sample was derived, under the assumption that this population has a log-normal distribution (EFSA PPR Panel, 2010).

Statistical estimates of percentiles for the theoretical populations from which samples were derived can be made using the formula:

$$\exp\left[\bar{x} + t_{n-1,a} * S * \sqrt{(1 + 1/n)}\right]$$

where $\bar{x}$ is the mean of the natural logarithms of the sample measurements, S is the standard deviation of the logarithms of the sample measurements, t_{n-1} is a t statistic with $n-1$ degrees of freedom (n being the number of measurements in the sample) and a is the relevant percentile.

The reason for including the statistical estimates of population parameters is that sample percentiles may, by chance, be unrepresentatively low, especially when the sample is relatively small and it is a high percentile that is being estimated. However, it would be reasonable to depart from this default method if, for example, there were good evidence that the assumption of an underlying log-normal distribution was inappropriate (e.g. a demonstration that the sample measurements deviated significantly (in statistical terms) and importantly (not just because of a single outlying value) from log-normality).

Where the quality and relevance of the supporting dataset can be clearly established, statistical methods should be used to explore possible relationships between observed exposure and other variables. Quantile regression (Koenker, 2005) is a non-parametric method which gives an independent estimate for every percentile. As long as the percentile is well within the range of measured data, the resulting fit can be expected to be more robust than one obtained from ordinary least squares regression. In particular, it will not depend on the actual choice of the value substituted for non-detects and does not assume the variability to be independent of the amount of active substance handled. Therefore, quantile regression is preferred over least squares regression.

Where only a small sample of relevant exposure measurements is available (less than minimum specified in OECD No 9), a decision must be made whether or not the dataset is adequate to support a valid risk assessment. If it is used, it may be necessary to make additional allowance for uncertainty in percentile estimates (e.g. by using upper confidence limits for estimated percentiles or a higher than normal percentile from the sample of measurements).

The agreed selection rule considers the higher value of the sample and the percentile estimate as long as this value is below the sample maximum. Otherwise, the sample maximum should be chosen.

4.4. Step 4: higher tier exposure assessment

Ad hoc methods (e.g. probabilistic) may also be used for higher tier exposure assessment where risk assessments using standardised methods give inadequate reassurance of safety. However, this should be done only if there is convincing evidence that the *ad hoc* method will be more appropriate than the standardised method.

5. Default values proposed for the assessment

The following default values have been based on the PPR opinion (EFSA PPR Panel, 2010), unless otherwise specified.

5.1. Body weights

In all calculations, it should be assumed, as a default, that adults have a body weight (bw) of 60 kg and that default body weight for children less than three years old is 10 kg.

- Adult body weight 60 kg
- Child body weight (less than three years old) 10 kg

A default body weight value of 60 kg is proposed in this Guidance to cover a range of professionally exposed adults including teenagers and females. The proposed value is in line with the recent HEEG opinion[6].

According to the EFSA Guidance on default values[7], a body weight of 70 kg should be used as default for the European adult population for consumer risk assessment (over 18 years old). However, when a particular subpopulation is identified as a focus for the risk assessment, actual data for this specific group should be used instead of the default value.

Selection of the 10 kg bw value for children is assumed to represent a worst-case scenario for the scenarios considered for children up to 11 years old exposed as residents and bystanders. Children less than a year old, which would be represented by a lower body weight, are normally not expected to be exposed through entry into treated fields (especially via the dermal route), in addition to playing on lawns and hand to mouth exposure.

5.2. Breathing rates

Where values for potential inhalation exposure are given as concentrations per cubic metre of air, an assumption must be made about the person's breathing rate in order to derive an estimate of the inhaled amount and systemic exposure.

For longer term exposures (i.e. of residents to vapours), the daily inhalation breathing rate should be taken as that shown in Table 3.

[6] HEEG opinion: Default human factor values for use in exposure assessments for biocidal products. http://echa.europa.eu/documents/10162/19680902/heeg_opinion_17_default_human_factor_values_en.pdf

[7] Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579.

Table 3: Daily inhalation rates (for longer term exposures) (modified from EFSA PPR Panel, 2010, based on US EPA, 2009)

Age group	Daily inhalation rate, adjusted for body weight (m^3/day/kg)
< 1 year	1 to < 3 years: 1.07 (worst-case scenario across the available scenarios up to 11-year-old children)
1 to < 3 years	
11 to < 16 years	Adults (including adolescents ≥ 11 years old): 0.23
Adults	

As for body weights, the inhalation rate of children aged one year to less than three years was selected to also be protective for other age groups. The inhalation rate of children less than one year old is higher; however, if considered together with the dermal exposure of the relevant exposure of children aged one year to less than three years (not relevant for children less than one year old), this would overestimate the total exposure, which is not considered appropriate.

For exposures which could occur predominantly over a shorter period, typically less than 30 minutes in duration, during which activity could be markedly more intense than the daily average (i.e. of bystanders to spray drift), higher values should be assumed, as shown in Table 4.

Table 4: Hourly inhalation rates (for acute exposures) (modified from EFSA PPR Panel, 2010, based on US EPA, 2009)

Age group	High intensity hourly inhalation rate, adjusted for body weight (m^3/h/kg)
< 1 year	1 to 3 years: 0.19 (worst-case scenario across the available scenarios up to 11-year-old children)
1 to 3 years	
11 to < 16 years	Adults (including adolescents ≥ 11 years old): 0.04
Adults	

Where operator and worker exposure values need to be estimated for a whole working day, an average breathing rate of 1.25 m^3/h should be used (HEEG Opinion).

5.3. Average air concentrations

The guidance set out in this section relates primarily to estimation of exposures to active substances with vapour pressures (preferably at 25 °C) less than 10^{-2} Pa. Average air concentrations in the 24 hours following application should be estimated as follows (Siebers et al., 2003; PSD 2008, bystander exposure guidance available at

http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/data-requirements-handbook/changes-to-the-operator-exposure-area-of-the-psd-website.htm):

- Substances with low volatility having a vapour pressure of < 5 × 10^{-3} Pa (the default average concentration in air in the 24 hours after application is 1 µg/m³).
- Moderately volatile substances with a vapour pressure between 5 × 10^{-3} Pa and 10^{-2} Pa (the default average concentration in air in the 24 hours after application is 15 µg/m³).

For active substances with vapour pressures ≥ 10^{-2} Pa, an *ad hoc* approach may be required.

5.4. Hectares treated per day

Table 5 shows default values for area treated per day, in hectares, depending on the type of crop and the application technique. The area treated reflects the technical standard of the equipment used in the original studies underpinning exposure data. In practice, the treated area will depend on the type of equipment used. The assessments proposed for operators, given modern equipment, are also considered to cover the assessment of less modern equipment in correlation with smaller areas treated per day and using smaller amounts of PPPs. The values used for the proposed models should not be adjusted for smaller areas treated with less modern equipment.

For crops not reported in Table 5, further justifications have to be provided by the applicant to show the most appropriate scenario to bridge the information.

Table 5: Area treated per day

Crops	**Area treated per day (ha)**	
	Hand-held equipment [(a)]	**Vehicle-mounted equipment**
Bare soil [(b)]	4/1	50
Berries and other small fruits (low)	4/1	50
Brassica vegetables	4/1	50
Bulb vegetables	4/1	50
Cane fruit	4/1	10
Cereals	4/1	50
Citrus fruit	4/1	10
Fruiting vegetables	4/1	50
Golf course turf or other sports lawns	4/1	50
Grassland and lawns	4/1	50
Grapes	4/1	10
Hops	4/1	10
Leaf vegetables and fresh herbs	4/1	50
Legume vegetables	4/1	50
Oilfruits (high crops)	4/1	10
Oilseeds	4/1	50
Ornamentals	4/1	10
Pome fruit	4/1	10
Root and tuber vegetables	4/1	50
Stone fruit	4/1	10
Tree nuts	4/1	10

(a): The first value should be used for hand-held application using tank sprayers with lances and the second value for other equipment (e.g. knapsack sprayers in low or high crops); for upwards spraying with hand-held equipment on dense foliage (late season), the area treated is 1 ha.

(b): In the exposure calculator (see Appendix E) there are no specific data on bare soil; however, it was considered that for spraying application downwards on soil (e.g. herbicides in pre-emergence) the same data as for application in low crops, tractor mounted, can be used, with the exception that no relevant re-entry exposure is foreseen. Planting activities in a bare soil are not covered by the present Guidance.

Exposure values for granule application are based on old values covering a maximum of approximately 20 hectares (PHED, 1992).

In the exposure calculator, the selection of the scenario will automatically redirect to the appropriate treated area per day.

5.5. Exposure durations

- Operator: 8 hours.
- Worker: 2 hours (default inspection activities); 8 hours (other activities).
- Resident and bystander (for acutely toxic active substances (a.s.) only): 2 hours (default for resident on lawn; dermal, surface deposits), 0.25 hours (dermal, entry into treated crops) and 24 hours (inhalation from vapour).

For all groups, daily exposures include individual exposure event durations as detailed below. The frequency or overall duration of exposure is accounted for in the appropriate reference value: acute risks are assessed on a daily basis, while longer term risk assessments are assessed on the basis of repeated exposures over continuous period.

5.6. Absorption values

Dermal and oral percentages should be taken from the toxicological evaluation.

- Oral: if less than 80 %, the specific value should be considered in the exposure calculator; if above 80 %, the exposure calculator will automatically consider 100 % oral absorption (consider oral absorption for reference value derivation).
- Dermal: to be determined according to Guidance on Dermal Absorption-EFSA PPR Panel (2012). For the dermal absorption percentage to be used for the assessment of worker, resident and bystander exposure towards surface deposits, the higher of the values for the undiluted product and the in-use dilution should be used. The use of higher dermal absorption is based on the precautionary principle as no measured values for dried residues after application of dilutions are available.
- Inhalation: 100 %

5.7. Default surface area of body parts

In table 6 the default surface areas for body parts are reported:

Table 6: Default values for surface area of the various parts of the body at different ages (from the HEEG Opinion **"**Default human factor values for use in exposure assessments for biocidal products")

	INFANT irrespective of gender (based on female 6 to < 12 months old)	**TODDLER irrespective of gender (based on female 1 to < 2 years old)**	**CHILD irrespective of gender (based on female 6 to < 11 years old)**	**ADULT irrespective of gender (based on female 30 to < 40 years old)**
Body weight	8 kg	10 kg	23.9 kg	60 kg
Body part surface areas				
Hands (palms and backs of both hands)	196.8 cm^2	230.4 cm^2	427.8 cm^2	820 cm^2
Arms (both)	Upper = 352.6 cm^2 Lower = 229.6 cm^2 Total = 582.2 cm^2	Upper = 412.8 cm^2 Lower = 268.8 cm^2 Total = 681.6 cm^2	Upper = 772.8 cm^2 Lower = 496.8 cm^2 Total = 1 269.6 cm^2	Upper = 1 141.2 cm^2 Lower = 1 128.8 cm^2 Total = 2 270 cm^2
Head	344.4 cm^2	403.2 cm^2	529 cm^2	1 110 cm^2
Trunk (bosom, neck, shoulders, abdomen, back, genitals and buttocks)	1 533.4 cm^2	1 977.6 cm^2	3 376.4 cm^2	5 710 cm^2
Legs (both legs and thighs)	1 041.4 cm^2	1 219.2 cm^2	2 741.6 cm^2	5 330 cm^2
Feet (both)	246 cm^2	288 cm^2	604.9 cm^2	1 130 cm^2
Total body surface area	3 944.2 cm^2	4 800 cm^2	8 949.3 cm^2	16 370 cm^2

Tables 7–12 in US EPA/Exposure Factors Handbook, November 2011 (data based on US EPS 1985 and NHANES 2005–2006) informs that the 25th percentile surface area for adult male forearms is 1 320 cm^2 which equates to 6.8 % of the 25th percentile for the total body surface area for the male (19 300 cm^2). Therefore, it is assumed that the 25th percentile for the surface area of the forearms for females also equates to 6.8 % of the female 25th percentile for the total body surface area. Therefore, for the adult female, the surface area of both forearms is calculated to be 16 600 × 6.8/100 = 1 128.8 cm^2.

5.7.1. Use of personal protective equipment

According to "good plant protection practice" and considering occupational hygiene measures, first tier exposure assessments for operators should be performed using work clothing (a brief description is given in the glossary).

In exposure assessments, the following levels of penetration (the concept of penetration includes both penetration and transfer from surfaces) could be assumed for use of engineering/technical controls, clothing and PPE if no measured data are available in the relevant exposure model(s):

- Gloves—10 % for liquids and 5 % for solids—for operators; for workers a factor of 10 % can be considered for re-entry activities.
- Coveralls (whole body) or a single layer of work clothing ("work wear" covering arms, body and legs)—for operators 10 % (data on the additional protection from coated coveralls are not available). Certified protective coverall would reduce body dermal exposure for operators by a 5 % factor.
- Hoods and visors reduce dermal (head) exposure to 5 %, whereas hood only to 50 %.
- Respiratory protective equipment (RPE): depending on the type considered, inhalation exposure can be reduced to 10–25 %, and dermal exposure (head) to 80 %.

Further refinements with different factors could be considered at Member State level based on national conditions. The proposed penetration factors are given in Table 7.

Table 7: Default personal protective equipment (PPE) (modified from EFSA PPR Panel, 2010, based on Gerritsen-Ebben et al., 2007; van Hemmen, 2008)

Technical control/PPE item		**Penetration factor (by which exposure in absence of protection should be multiplied)**	**Specific exposure value affected**
Protective (chemical-resistant) gloves		Operators, liquids 10 %; operators, solids 5 %; workers, solids 10 %	Dermal exposure—hands only
Working clothing or uncertified cotton coverall		Operators 10 %	Dermal exposure—body only
Protective coverall (*this is used instead of working clothing/uncertified cotton coverall*)		Operators certified protective coverall 5 %	Dermal exposure—body only
Hood and visor (a)		Operators 5 %	Dermal exposure—head only
Hood		Operators 50 %	Dermal exposure—head only
RPE mask type	Filter type		
Half and full face masks	FP1, P1 and similar	25 % 80 %	Inhalation exposure Dermal exposure—head only
	FFP2, P2 and similar	10 % 80 %	Inhalation exposure Dermal exposure—head only

(a): Hood and visor are considered as an alternative to the RPE.
RPE, respiratory protective equipment.

In the AOEM, and in the models for granule application, the selection of certain PPE is already included (based on study data for actual exposure). In this case, the default factors given above for corresponding PPE should not be applied.

For other models, a certified coverall provides a 5 % penetration; the effect of wearing garments providing greater protection has to be considered separately from the exposure calculator and in discussion with Member State authorities as there is no harmonised classification of proposed factors.

6. Methods for first tier exposure assessment

6.1. Operator exposure

Exposure is estimated for the recommended conditions of use of the PPP. Exposure estimation for mixing/loading and the application is normally done separately. Both dermal and inhalation exposures are considered.

Dermal exposures are converted into systemic doses using appropriate dermal absorption percentages. Inhalation exposures are assumed to be completely absorbed (100 %). Exposure estimates for individual tasks are the sum of the dermal exposures and the inhalation exposures. Where an operator is expected to engage in both mixing/loading and application, exposures from these tasks are summed. The total exposure is divided by a standard body weight of 60 kg and then compared with the relevant reference values.

So far, models established over 20 years ago (e.g. UK POEM, German model) have been the standards to assess exposure of agricultural operators to PPPs, but they do not reflect current application techniques. A new predictive model for the estimation of agricultural operator exposure has been developed (AOEM, Großkopf 2012) on the basis of new exposure data to improve the current agricultural operator exposure and risk assessment in the EU. The new operator exposure model represents current application techniques and practices in EU Member States. Available exposure studies conducted between 1994 and 2009, and provided for authorisation of PPPs, were evaluated regarding quality criteria, e.g. conformance with Good Laboratory Practice (GLP) and compliance with OECD guidance. Exposure data and supplementary information from 34 studies were used for a statistical analysis of exposure factors. The statistical analyses resulted in six validated models for typical outdoor scenarios of pesticide mixing/loading and application. Currently, no data exist to confirm that the available mixing/loading values can be applied to an indoor scenario; however, activities during mixing/loading for outdoor and for indoor application should be comparable. The whole project report on the development of the new model (including the underlying study data and validation procedure) is published.

The AOEM was considered by the WoG as suitable for inclusion in the EFSA GD and its exposure calculator, as it reflects updated agricultural practices, including the use of PPE; furthermore, the criteria for the selection of the studies are transparent and allow reproducibility of the outcomes. Based on the nature of the new dataset, which is not comparable to old, i.e. existing, data, it was decided to replace the relevant scenario with the new data, if available.

For the assessment of operator exposure, the 75th percentile was considered appropriate (in addition, a model based on the 95th percentile was developed for future use). The model includes application techniques and scenarios for outdoor treatment of low and high crops, by vehicle-mounted/trailed or self-propelled sprayers or by hand-held spray guns and knapsack sprayers (see Tables 8 and 9).

Mixing/loading values from the AOEM may also be considered representative of other application methods in which product handling and equipment preparation tasks are comparable (e.g. weed wipers) as long as no further data are available. As a default, intended uses using hand-held application equipment should be calculated using knapsack and tank mixing and loading scenarios.

Table 8: AOEM scenarios with respective exposure in µg (prediction level: 75th percentile); TA: total amount of active substance applied per day (in kg a.s./day); protected body: exposure beneath one layer of work clothing (in the calculator full values are reported, not rounded as in the table below)

Mixing/ loading - tank		log exp = α·log TA + [formulation type] + constant
	hands	$\log D_{M(H)}$ = 0.77·log TA + 0.57 [liquid] + 1.27 [WP] - 0.29 [glove wash] + 3.12
	protected hands	$\log D_{M(Hp)}$ = 0.65·log TA + 0.32 [liquid] + 1.74 [WP] + 1.22
	body	$\log D_{M(B)}$ = 0.70·log TA + 0.46 [liquid] + 1.83 [WP] + 3.09
	protected body	$\log D_{M(Bp)}$ = 0.89·log TA + 0.11 [liquid] + 1.76 [WP] + 1.27
	head	$\log D_{M(C)}$ = log TA + 0.90 [liquid] + 1.28 [WP] + 1.79 [no face shield] - 0.98
	inhalation	$\log I_M$ = 0.30·log TA - 1.00 [liquid] + 1.76 [WP] + 1.57
Mixing/ loading - knapsack		75th percentile (above 1.5 kg a.s. linear extrapolation)
	hands	9495
	protected hands	18
	body	803
	protected body	25
	head	5
	inhalation	25
Downward spraying – vehicle-mounted		log exp = α·log TA + [droplets] + [equipment] + constant
	hands	$\log D_{A(H)}$ = log TA + 0.37 [normal droplets] - 1.04 [normal equipment] + 2.84
	protected hands	$\log D_{A(Hp)}$ = 0.54·log TA + 1.11 [normal droplets] + 0.29 [normal equipment] - 0.23
	body	$\log D_{A(B)}$ = log TA + 0.81 [normal droplets] - 1.43 [normal equipment] + 2.54
	protected body	$\log D_{A(Bp)}$ = log TA + 0.70 [normal droplets] - 1.09 [normal equipment] + 0.74
	head	$\log D_{A(C)}$ = log TA + 0.88 [normal droplets] - 0.53 [normal equipment] + 0.24
	inhalation	$\log I_A$ = 0.50·log TA + 0.01 [normal droplets] - 0.71 [normal equipment] + 0.72
Upward spraying – vehicle-mounted		log exp = α·log TA + [cabin] + constant
	hands	$\log D_{A(H)}$ = 0.89·log TA + 0.28 [no cabin] + 3.12
	protected hands	$\log D_{A(Hp)}$ = log TA - 1.55
	body	$\log D_{A(B)}$ = log TA + 0.48 [no cabin] + 3.47
	protected body	$\log D_{A(Bp)}$ = log TA + 0.23 [no cabin] + 1.83
	head	$\log D_{A(C)}$ = log TA + 1.89 [no cabin] + 1.17
	inhalation	$\log I_A$ = 0.57·log TA + 0.82 [no cabin] + 0.99
Downward spraying – hand-held		75th percentile (above 1.5 kg a.s. linear extrapolation)
	hands	1544
	protected hands	5
	body	88868
	protected body	8903
	head	12
	inhalation	26
Upward spraying – hand-held		log exp = α·log TA + [culture] + constant
	hands	$\log D_{A(H)}$ = 0.84·log TA - 0.83 [normal culture] + 4.26
	protected hands	$\log D_{A(Hp)}$ = log TA - 0.88 [normal culture] + 2.26
	body	$\log D_{A(B)}$ = 0.16·log TA - 1.29 [normal culture] + 6.08
	protected body	$\log D_{A(Bp)}$ = - 1.64 [normal culture] + 4.65
	head	$\log D_{A(C)}$ = 0.32·log TA - 1.09 [normal culture] + 3.27
	inhalation	$\log I_A$ = 0.83·log TA - 0.26 [normal culture] + 2.17

Table 9: AOEM scenarios with respective exposure in µg (prediction level: 95th percentile; acute exposure); TA: total amount of active substance applied per day (in kg a.s./day); protected body: exposure beneath one layer of work clothing (in the calculator full values are reported, not rounded as in the table below)

Mixing/ loading - tank		log exp = α·log TA + [formulation type] + constant
	hands	log $D_{M(H)}$ = 0.78·log TA + 0.45 [liquid] + 1.15 [WP] - 0.84 [glove wash] + 3.80
	protected hands	log $D_{M(Hp)}$ = log TA + 0.80 [liquid] + 1.81 [WP] + 1.50
	body	log $D_{M(B)}$ = 0.29·log TA + 0.65 [liquid] + 1.25 [WP] + 4.21
	protected body	log $D_{M(Bp)}$ = log TA + 0.37 [liquid] + 1.50 [WP] + 1.79
	head	log $D_{M(C)}$ = log TA + 0.50 [liquid] + 0.35 [WP] + 1.25 [no face shield] + 0.70
	inhalation	log I_M = 0.02·log TA – 0.96 [liquid] + 1.28 [WP] + 2.41
Mixing/ loading - knapsack		95th percentile (above 1.5 kg a.s. linear extrapolation)
	hands	25483
	protected hands	164
	body	2787
	protected body	103
	head	11
	inhalation	26
Downward spraying – vehicle-ounted		log exp = α·log TA + [droplets] + [equipment] + constant
	hands	log $D_{A(H)}$ = 0.73·log TA + 0.61 [normal droplets] - 0.21 [normal equipment] + 2.96
	protected hands	log $D_{A(Hp)}$ = 0.12·log TA + 1.79 [normal droplets] + 2.19 [normal equipment] - 0.46
	body	log $D_{A(B)}$ = log TA + 1.51 [normal droplets] - 0.82 [normal equipment] + 1.94
	protected body	log $D_{A(Bp)}$ = log TA + 1.05 [normal droplets] - 0.77 [normal equipment] + 0.47
	head	log $D_{A(C)}$ = log TA + 1.03 [normal droplets] - 1.12 [normal equipment] + 1.16
	inhalation	log I_A = 0.58·log TA + 0.33 [normal droplets] - 1.14 [normal equipment] + 1.27
Upward spraying – vehicle-mounted		log exp = α·log TA + [cabin] + constant
	hands	log $D_{A(H)}$ = log TA + 0.48 [no cabin] + 3.32
	protected hands	log $D_{A(Hp)}$ = log TA + 0.08 [no cabin] + 2.88
	body	log $D_{A(B)}$ = log TA + 0.79 [no cabin] + 3.92
	protected body	log $D_{A(Bp)}$ = log TA + 0.15 [no cabin] + 2.21
	head	log $D_{A(C)}$ = log TA + 1.56 [no cabin] + 2.29
	inhalation	log I_A = log TA + 0.60 [no cabin] + 1.32
Downward spraying – hand-held		95th percentile (above 1.5 kg a.s. linear extrapolation)
	hands	4213
	protected hands	22
	body	137007
	protected body	62630
	head	85
	inhalation	26
Upward spraying – hand-held		log exp = α·log TA + [culture] + constant
	hands	log $D_{A(H)}$ = 0.77·log TA - 0.47 [normal culture] + 4.41
	protected hands	log $D_{A(Hp)}$ = log TA - 0.51 [normal culture] + 2.61
	body	log $D_{A(B)}$ = 0.01·log TA - 1.09 [normal culture] + 6.34
	protected body	log $D_{A(Bp)}$ = - 1.99 [normal culture] + 5.27
	head	log $D_{A(C)}$ = 0.33·log TA - 0.59 [normal culture] + 3.50
	inhalation	log I_A = 0.60·log TA - 0.26 [normal culture] + 2.52

Further models are available (adapted from EFSA PPR Panel, 2010) covering partly additional scenarios (e.g. granular application). It should be taken into account that most of these data are relatively old. However, in order to cover additional scenarios or certain circumstances, these models could be used as well.

The estimated exposures from defined work tasks are assumed to depend on the amount of active substance handled in the tasks (in a few cases, as indicated in Table 10, specific exposures cover a combination of mixing/loading and application, in which case the summation exercise is not required). The estimated exposure is the product of the specific exposure in mg (or µg) exposure/kg a.s. handled (Table 10 or Table 11, as appropriate), the area treated (ha/day) (Table 5) and the recommended amount of active substance applied (kg a.s./ha).

Table 10: Additional models for specific exposures during loading of plant protection products applied as granules[(a)] (adapted from EFSA PPR Panel, 2010)

Application equipment	Formulation type (see appendix A for the codes)	Type of exposure	mg exposure/kg a.s. loaded		Model	Comments
			75^{th} percentile	95^{th} percentile		
Vehicle-mounted	GR, FG	Hands	0.0015	0.0069	PHED	Scenario "without RPE/PPE" includes wearing protective gloves
		Body	0.0162	0.0427	PHED	Scenario "without RPE/PPE" includes wearing workwear
		Inhalation	0.0208	0.0784	PHED	None

(a) For manual application of granule formulations, the original exposure data were derived considering the use of PPE (gloves and coverall). For the non-PPE scenario, a 100 times higher value is considered for hands and body.

a.s., active substance; FG, fine granules; GR, granules; PHED, Pesticide Handler Exposure Database; PPE, personal protective equipment; RPE, respiratory protective equipment.

The lack of data with regard to automated application does not allow the consideration of a no exposure scenario for mixing/loading in this context.

Table 11: Additional models for specific exposures during application of plant protection products applied as granules[(a)] (outdoor/indoor)

Application method	Application equipment	Type of exposure	mg exposure/kg a.s. applied		Model	Comments
			P75	P95		
Broadcast application of granules	Vehicle-mounted	Hands	0.0004	0.0013	PHED	Scenario "without RPE/PPE" includes wearing protective gloves
		Body	0.0047	0.0151	PHED	Scenario "without RPE/PPE" includes wearing workwear
		Inhalation	0.0012	0.0045	PHED	None
In-furrow application of granules	Vehicle-mounted	Hands	0.0004	0.0013	PHED	Scenario "without RPE/PPE" includes wearing protective gloves
		Body	0.0047	0.0151	PHED	Scenario "without RPE/PPE" includes

Application method	Application equipment	Type of exposure	mg exposure/kg a.s. applied		Model	Comments
			P75	P95		
						wearing workwear
		Inhalation	0.0012	0.0045	PHED	None
Manual application of granules	Manual (hand held equipment)	Hands	28.5320	94.3636	PHED	Scenario "without RPE/PPE" includes wearing protective gloves; value is for combination of loading and application
		Body	68.8708	253.4433	PHED	Scenario "without RPE/PPE" includes wearing workwear; value is for combination of loading and application
		Inhalation	0.4677	1.5251	PHED	Value is for combination of loading and application

(a) For manual application of granule formulations, the original exposure data were derived considering the use of PPE (gloves and coverall). For the non-PPE scenario, a 100 times higher value is considered for hands and body.

a.s., active substance; FG, fine granules; GR, granules; PHED, Pesticide Handler Exposure Database; PPE, personal protective equipment; RPE, respiratory protective equipment.

The possibility of using water-soluble bags was considered. Exposure to PPPs during mixing and loading is likely to be limited but not negligible. Based on expert judgement and approaches at the national level, the WoG decided that the default exposure deriving from mixing and loading activities of water-soluble bag should be assumed to be 10 % of the corresponding formulation (the option is not included in the exposure calculator).

6.2. Worker exposure

Exposure of workers must be estimated for activities that involve contact with treated crops. Such contact may occur when workers re-enter treated areas after application of a PPP (e.g. for crop inspection or harvesting activities). In addition, worker exposure can arise from other activities such as packaging, sorting and bundling.

The underlying studies for the worker exposure model show a high level of uncertainties in terms of quality and reliability of data. For the exposure calculator, the longer term exposure was only considered. It is noted that the database contains some weaknesses because of the limited dataset and the statistical uncertainties.

Exposure should be estimated for activities that could entail contact with treated crops, either by re-entering a treated area after application (e.g. for crop inspection/harvesting activities) or through other activities such as sorting and bundling. Currently, the available data allow calculations for re-entry only immediately after the application solution has dried. No further data are available. Any further refinement if data additional data are available to companies will have to be done manually.

The main routes of exposure during post-application activities are dermal and inhalation, and the sources of exposure are contact with foliage (here used to include fruits as well as leaves), soil and possibly dust. Oral exposure may occur secondarily to dermal exposure, through hand to mouth transfer. However, for workers, potential exposure by this route is generally assumed to be negligible in comparison with that via skin and inhalation.

Most crop maintenance and harvesting activities include frequent contacts with the foliage of the crop. Therefore, dermal exposure is considered to be the most important exposure route during these re-entry activities. The level of resultant exposure (for a given activity) depends on the amount of residue on foliage, the intensity of contact with the foliage and the overall duration of contact.

Inhalation exposure may be to vapour and/or airborne aerosols (including dust). After outdoor application of PPPs and after the spray solution has dried, there will be more rapid dissipation of vapour and aerosols, leading to lower inhalation potential than from indoor treatments (where the inhalation route is a relevant route for re-entry workers), such as those made to crops grown in glasshouses. Therefore, worker exposure estimates for the inhalation route after outdoor applications are only necessary in exceptional cases (e.g. for volatile substances). In this case *an ad* hoc approach is necessary.

There are also some re-entry situations where exposure to soil-borne residues occurs in the absence of contact with treated foliage, for example workers using compost treated with an insecticide, or during manual harvesting of root crops (see Appendix F for further information) However, in most situations the contribution of soil residues to the total exposure is expected to be significantly less than that from dislodgeable foliar residues. Where there is concomitant exposure to dislodgeable foliar residues, exposure from contact with soil residues can be ignored.

When the first tier methods described in this section are applied, the same estimates of worker exposure are used for both acute and longer term risk assessment. However, if worker exposures are estimated from *ad hoc* data, then the exposure estimates used for acute and longer term risk assessments will normally be different.

To derive a total estimate of worker exposure, it is necessary to sum the components of exposure from each relevant source and route. The methods for estimating exposures assume that the worker will wear no PPE (Commission Regulation (EU) No 284/2013). Where the risk assessor is confident that normal workwear will comprise coveralls or long-sleeved jackets and trousers (arms, body and legs covered), this can be used. If it is considered that workers can be reliably expected to use PPE (body and hands covered), then allowance for this can be made in exposure estimation by application of respective transfer coefficients (TC) as specified in Table 13.

6.2.1. Dermal exposure of workers

Dermal exposure from contact with residues on foliage should be estimated as the product of the dislodgeable foliar residue (DFR), the transfer coefficient (TC) and the task duration (T):

Potential dermal exposure (PDE) in mg a.s./day = (DFR [µg/cm^2] × TC [cm^2/h] × T [h/day])/1 000

The default value for time of exposure should be taken as eight hours for harvesting and maintenance type activities and two hours for crop inspection and irrigation-type activities.

To convert estimated dermal exposures to corresponding systemic exposures, exposure should be multiplied by a dermal absorption factor, derived from the toxicological assessment. The default value used for the dermal absorption factor should be the higher of the values for the product and for the in-use dilution (normally no dermal absorption values are available for dried dilutions) (EFSA Guidance Document on Dermal Absorption, 2012).

6.2.2. Dislodgeable foliar residue (DFR)

The amount of residue on foliage depends on several factors, including the application rate, application efficiency (how much reaches and is retained on the target), crop type and the amount of foliage (leaf area index). Dissipation of residues on crop foliage over time depends on the physical and chemical properties of the applied PPP, and also on environmental conditions. Where experimentally determined DFR data are not available, the initial DFR (DFR0 is the DFR just after application, it assumes that no dissipation will take place and that everything is dislodgeable) in a first tier assessment should assume 3 µg active substance/cm^2 of foliage/kg a.s. applied/ha; the value provided was regarded as highly conservative (EUROPOEM II, 2002).

The exposure calculator provides the possibility of entering different DFR values when available from experimental data.

Allowance may be introduced to refine the assessment for dissipation (decay) of the active substance on the foliage if the exact nature of the dissipation over time is known. If no data are available on the degree of dissipation, it may be assumed that active substances which are organic chemicals, and for which there is evidence of breakdown e.g. by photolysis or hydrolysis in soil or water, will dissipate with a half-life of 30 days. For other categories of active substance DFR0 (i.e. the residue available directly after application when dry) should be used for calculations.

6.2.3. Multiple application factor (MAF)

A realistic worst-case scenario is to consider re-entry after the final treatment has been made to a crop. Therefore, where approval is sought for multiple treatments, the assessment should consider the potential accumulation of DFR from successive treatments. If no experimental data are available, and an active substance is assumed to dissipate with a half-life of 30 days (this value differs from that proposed in the birds and mammals opinion (EFSA, 2008) because it was decided to follow a more conservative approach based on the available data (see Appendices C and D of this Guidance) indicating possible DT50 values (the time required for 50 % of the initial concentration to dissipate) up to and exceeding 30 days for some active substances), the dissipation should be taken into account by application of an appropriate multiple application factor (MAF), examples of which are given in Table 12 (see also Appendix B).

The default value of 30 days should be used only if no data are reported for DT50 or half-life in Appendices D and E of this Guidance. For new active substances, it will be possible to include new experimental data in the exposure calculator when available; refined calculations with specific values are not considered necessary when exposure estimates in the first tier are below the established trigger.

Table 12: Multiple application factors, assuming a default dissipation half-life of 30 days (EFSA PPR Panel, 2010)

Interval between applications (days)	Number of applications											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
7	1.0	1.9	2.6	3.2	3.7	4.2	4.5	4.9	5.1	5.4	5.6	5.7
10	1.0	1.8	2.4	2.9	3.3	3.6	3.9	4.1	4.2	4.4	4.5	4.5
14	1.0	1.7	2.2	2.6	2.9	3.1	3.2	3.3	3.4	3.5	3.5	3.5
21	1.0	1.6	2.0	2.2	2.4	2.5	2.5	2.6	2.6	2.6	2.6	2.6

6.2.4. Transfer coefficient (TC)

The transfer of residues from the plant surface to the clothes or skin of the worker should be taken into account, regardless of the product applied, the level of exposure depending on the intensity and duration of contact with the foliage. This is determined by the nature and duration of the activity during re-entry. Therefore, it is possible to group various crop habitats and re-entry activities.

$$TC\ (cm^2/h) = PDE\ (mg/h)/DFR\ (mg/cm^2)$$

The indicative TC values in Table 13 are based and modified from EUROPOEM II (2002) and in consideration of US EPA values (Appendix G) and apply to both outdoor and indoor scenarios. These values should be used in first tier assessments of potential dermal exposure for the scenarios specified. Three sets of TC values are given, according to whether or not it can be assumed that the worker will wear clothing that covers the arms, body and legs. It is assumed that harvesting is performed with bare hands or with gloves, and that dermal exposure to the body is reduced 10-fold by clothing covering the arms, body and legs. When no PPE and no workwear are worn, exposures may be higher than these estimates and potential exposure should be estimated using the values in the fourth column of Table 13.

These TC values may be extrapolated to other re-entry scenarios, where the intensity and duration of contact with the foliage is judged to be similar.

Table 13: Transfer coefficients (TCs) (modified from EUROPOEM II (2002) considering US EPA, 2012; for both outdoor and indoor scenarios)

Crop	Nature of task [(a)]	Main body parts in contact with foliage	TC (cm^2/h), total potential exposure	TC (cm^2/h) assuming arms, body and legs covered (workwear; bare hands)	TC (cm^2/h), covered body (workwear) and gloves (PPE)	Applicable for the following crops
Vegetables	Reach/pick	Hand and body	5 800	2 500	580	Brassica vegetables, fruiting vegetables, leaf vegetables and fresh herbs, legume vegetables, bulb vegetables
Tree fruits	Search/reach/ pick	Hand and body	22 500	4 500	2 250	Citrus, cane fruits, oilfruits, pome fruits, stone fruits, tree nuts
Grapes [(b)]	Harvesting and other activities (e.g. leaf pulling and tying)	Hand and body	30 000	10 100	No justified proposal possible (data missing)	n.a.
Strawberries	Reach/pick	Hand and forearm	5 800 [(c)]	3 000	750	Berries and other small fruit, low
Ornamentals	Cut/sort/ bundle/carry	Hand and body	14 000	5 000	1 400	Ornamentals and nursery
Golf course, turf or other sports lawns	Maintenance	Hand and body	5 800	2 500	580	n.a.

Crop	Nature of task [(a)]	Main body parts in contact with foliage	TC (cm^2/h), total potential exposure	TC (cm^2/h) assuming arms, body and legs covered (workwear; bare hands)	TC (cm^2/h), covered body (workwear) and gloves (PPE)	Applicable for the following crops
General [(c)]	Inspection, irrigation	Hand and body	12 500 [(d)] 7 500 [(e)]	1 400 [(d)]	No justified proposal possible	Cereals, grassland and lawns, hops, oilseeds, root and tuber vegetables, sugar beets, etc.

(a): The list of tasks is reported in the glossary.

(b): US EPA data were used even if the underline data are not available as it is clear that grape harvesting might be a scenario of concern for which EU data are missing. As for inspection activities, the US EPA values are considered to be appropriate, in absence of supporting data, when compared with the exposure values for other tasks.

(c): No reliable data for this scenario are available, therefore the TC of vegetable potential exposure is proposed as surrogate.

(d): US Re-entry Agricultural TF data were used, recalculated by Health and Safety Executive to account for 75th percentile instead of arithmetic mean (see technical report comment 211).

(e) US Re-entry Agricultural TF data were used; the value proposed is the arithmetic mean of the 75th percentiles from the two studies considered, lower legs and arms uncovered (see technical report comment 211).

n.a., not available; PPE, personal protective equipment.

In Appendix H, the TC values proposed in this Guidance and the values used in the US EPA are compared.

Access to the scientific data underlying the TC values is in many cases very limited, as was the ability of the WoG to access all the relevant original data (e.g. both the US EPA (2000) and data reported in the EUROPOEM II report). However, the decision was taken to make available a tool for the exposure assessment, highlighting though the need for more new and transparent data. In addition, other parameters supposedly impact on the transfer, such space between rows of the crop, meteorological conditions (humidity, wind, etc.); however, the values proposed are based on currently available data.

6.2.5. Inhalation exposure of workers

Potential exposure to a volatilised a.s. decreases with time as its concentration is reduced, by absorption into the plant, degradation or loss to the environment. Although, in many cases, inhalation exposure is likely to contribute less to total potential exposure than that by the dermal route, in crops grown e.g. in greenhouses the inhalation exposure has to be calculated. For this purpose, task-specific inhalation factors should be used for first tier exposure assessments (e.g. relating to harvesting tasks indoors and to re-entering greenhouses where pesticide droplets may remain airborne after the treatment). Inhalation exposure for this re-entry scenario may be predicted by the following:

Potential inhalation exposure [mg a.s./h inhaled] = application rate [kg a.s./ha] × Task Specific Factor [ha/h × 10^{-3}]

The Task Specific Factors can be used in the first tier of the exposure and risk assessment: they have been estimated for a small set of exposure data for harvesting and re-entry in ornamental greenhouses. Task Specific Factors are as set out in Table 14.

Table 14: Indicative inhalation Task Specific Factors for protected crops (van Hemmen et al., 2002)

Task	Task Specific Factor (ha/h × 10^{-3})
Cutting	0.1
Sorting and bundling	0.01
Re-entering greenhouses after low-volume-mist application	0.03 (8 hours after application)
Re-entering greenhouses after roof fogger application	0.15 (16 hours after application)

The default value for duration of exposure is eight hours for activities such as harvesting, cutting, sorting, etc., and two hours for crop inspection or irrigation activities.

This approach may be used for low and moderately volatile pesticides, in which case levels of inhalation exposure (vapour and dust) are expected to be low in comparison with dermal exposure. Additional data may be required to estimate inhalation exposures for products applied as vapours and for volatile pesticides, which are outside the scope of this Guidance.

It is noted that the current version of the exposure calculator does not include these factors (except for some indoor re-entry scenario where information is available) as greenhouse application data are not available.

For uses other than ornamentals no inhalation Task Specific Factors are available. The applicability of the factors in Table 14 to other protected crops needs to be assessed on a case-by-case basis.

6.3. Resident and bystander exposure

The dataset available for assessing resident and bystander exposure is rather limited, being based on only a few studies, some of which performed in the 1980s. Furthermore, some of the US EPA values used to conclude on these assessments are not completely reported (raw data missing).

The WoG recommends that further data are produced to refine the proposed assessment.

Four pathways of exposure are considered (EFSA PPR Panel, 2010):

- spray drift (at the time of application)
- vapour (may occur after the PPP has been applied)
- surface deposits
- entry into treated crops.

Summing all the exposure pathways, each one being conservative (considering high percentiles of exposure), would result in an overly conservative and unrealistic result. This is particularly true for bystanders, considering that it is extremely unlikely that all exposures occur together. However, for residents, it might be appropriate to sum up the mean exposures from each pathway, where available.

In the opinion of the PPR Panel (EFSA PPR Panel, 2010), the best available dataset indicated for arable crops is that reported by Lloyd and Bell (1983). For orchard crops and vines, the most appropriate dataset is Lloyd et al. (1987).

The exposure values derived from the publication by Lloyd and Bell (1983) for tractor-mounted boom-spraying relate to exposures at a distance of 8 m downwind from a passing sprayer. To account for additional, more distant, passes of a sprayer, and for the possibility of closer proximity than 8 m, the Panel proposed that the dermal values be increased by a factor of 10 (however, data behind this proposal are limited). Similarly, from currently available data, the Panel considered that there does not appear to be a need for similar adjustment of exposures by inhalation.

However, after the publication of the PPR opinion, further data became available. In particular, the BREAM calculator was developed in the UK for assessing resident and bystander exposure after application in low crops. An exposure calculator was prepared, allowing an estimation of the mean, 25th, 75th and 95th percentile drift and exposure values for specific scenarios.

Data from the BREAM calculator and the scenarios investigated are set out in Table 15.

Table 15: Data derived using the BREAM calculator and the scenario specified

BREAM calculator input	Value	Notes
Nozzle type	FF03110	Conventional flat fan nozzle. It is the only dataset currently available. From other drift data, it is clearly not the worse case nor the best case
Number of nozzles	48	Represents single pass of a 24-m boom. Further upwind passes could possibly contribute additional drift, but the wind conditions will not be identical and the additional contribution from including more upwind nozzles or passes is relatively small
Boom height	0.7 m	The optimum height is 0.5 m, but anecdotal evidence suggests modern practice involving large sprayers travelling at fast forward speeds exceeds this. Spray drift increases with boom height
Forward speed	12.6 km/h	Considered to be the upper end of the current "average" in the UK based on expert opinion (i.e. 3.5 m/s, hence 12.6 km/h). A 2004 UK survey showed that between 15 and 20 % of the area treated by large or self-propelled sprayers was done using average speeds in the range 13–16 km/h
Spray concentration	1 g a.s./L spray	Used to generate unit values which can be adjusted by product-specific values
Crop height	Short	The model does not yet support estimation of exposure from spraying other crops
Wind speed	2.7 m/s	Upper limit of what is considered acceptable for spraying in the UK Code of Practice
Bystander type	Child and adult	Data collected on adult and child mannequins. Adult were 1.87 m tall. Child manikins were 1.03 m tall (i.e. about median height for a four-year-old child)
Exposure route	Dermal and inhalation	None
Dermal absorption	100 %	Used to give an estimate of the external dose, which later can be adjusted by appropriate dermal absorption values
Inhalation rate	Bystanders (inhalation reflective of high intensity activity)	None
	Children 1.90 m^3/h	The body weight assumed in this Guidance is 10 kg, which is representative of children around one year old. Therefore, to be compatible with this body weight, an average high activity breathing rate of 0.190 m^3/h/kg bw should be used, and the rate per hour becomes 0.190 m^3/h/kg bw × 10 kg = 1.90 m^3/h
	Adults 2.4 m^3/h	i.e. 0.04 m^3/h/kg bw × 60 kg
	Residents (daily average inhalation rate)	None
	Children 0.45 m^3/h	The body weight assumed in the Guidance is 10 kg, which is representative of children around one year old. Therefore, to be compatible with this body weight, an average breathing rate of 1.07 m^3/h/kg bw should be used, and the rate per hour becomes 1.07 m^3/day/kg bw × 10 kg bw/24 h = 0.45 m^3/h
	Adults 0.575 m^3/h	i.e. 0.23 m^3/kg bw/day × 60 kg bw/24 h

BREAM calculator input	Value	Notes
Distance from source	2 m	Considered to represent a realistic worst-case distance. For example, this could represent a sprayer operating at the edge of a field with a resident/bystander in a garden separated from the field by a simple wire fence and with both the spray operator and resident/bystander unaware of each others actions

Note: a typical F11003 nozzle operating at 3 bar, at the above forward speed would apply about 120 L/ha which is 12 mL/m^2, and at the spray concentration of 1 g/L. Assuming above, this would deliver 120 g/ha or 12 mg/m^2. The model is a good predictor for short crop and short vegetation.

The WoG decided to adopt the BREAM parameters for arable crops, as they were considered more appropriate for this scenario than those reported by Lloyd and Bell (1983).

For estimating exposure from surface deposits, ground sediments based on drift for application in orchards are taken from Rautmann/Ganzelmeier; for arable crops, respective data are from the BREAM project.

Dermal and oral absorption percentages should be taken from the toxicological evaluation. For the dermal absorption percentage (resulting from contact with the spray solution) used for resident and bystander exposure assessment, the value for the in-use dilution should be used, and, for contact with drift deposits, the higher of the two values should be used.

The calculator will allow adjustments based on drift reduction for upwards and downwards spraying for both residents and bystanders.

An adjustment for light clothing for residents and bystanders is proposed: assuming that the trunk is covered, that the trunk represents 36 % of the body surface area and that the clothing gives 50 % protection (in line with the EUROPOEM 1996 report for clothes), there would be a reduction of 18 % for adults and 18 % for children (trunk represents 35.7 % of the body surface area). This adjustment is taken into account for estimates of potential dermal exposure arising from spray drift only.

The possibility of refining the exposure assessment based on increases of the distance from the source of 5 and 10 m is given in the calculator.

6.3.1. Resident exposure

For exposure through treatment of nearby crops, four pathways of exposure should be considered (spray drift, vapour, surface deposit, entry into treated crops); in principle, residential exposure should be based on the 75th percentile estimates. However, summing the individual 75th percentile exposures does not seem appropriate, whereas summing the means does seem reasonable for assessing repeated exposure. On this basis, both the 75th percentile and mean values need to be calculated for each residential exposure (currently only available for spray drift and drift deposit), the 75th percentile will be assessed separately and the means will be summed up (each calculated exposure is likely providing a conservative estimate, therefore the final resident exposure should be the sum of the mean values of each exposure pathway).

(For repeated applications on tree crops, it may not be possible to specify the “season” in the data entry calculator as “with” or “without leaves”. The calculator will default to the worst-case scenario, for which there is some uncertainty.)

6.3.1.1. Spray drift

The exposures from spray drift should be calculated using the following equation:

Dermal exposure × dermal absorption percentage + inhalation exposure where the dermal absorption percentage is the value for the in-use dilution taken from the toxicological evaluation, and the dermal and inhalation exposures are those shown in Tables 16 and 17.

For arable crops, it was agreed that BREAM data provide a better estimate of exposure and are more representative of modern practices than data from Lloyd and Bell (1983). In addition, BREAM data provide drift data for children (using mannequins representative of 4-year-old children). The BREAM results do not provide values for upwards spraying.

For orchard crops and vines, the most appropriate dataset out of the three presented is the dataset for conventional nozzles (no drift reduction technologies) applying 470 L/ha from a report by Lloyd et al. (1987) for an 8-m distance downwind from the middle of the tree trunk. This dataset gave the highest drift exposures in that report. No adjustment to the exposure values for orchard crops and vines is proposed, since the measurements in the report by Lloyd et al. (1987) relate to application across an entire orchard, and the layout of orchards and vineyards and the way equipment is operated (e.g. when at the edge of the orchard, spray is directed only into the crop) makes the values suitable for a resident located about 5 m from the edge of a field, assuming the space from the tree trunk to the edge of the field is at least 3 m; moreover, these data form a significant part of those included in EUROPOEM for this scenario, and are preferred to the others, as they were generated under more representative conditions.

However, it should be taken into account that these data are relatively old and that data for different distances are not available. The WoG recommends that further data are produced to refine the proposed assessment.

The dermal and inhalation exposures (75th percentile and mean values) are as shown in Tables 16 and 17.

Table 16: Dermal and inhalation exposures for residents (75th percentile from data on potential dermal and inhalational exposures) (adapted and amended from EFSA PPR Panel, 2010)

Method of application (distance from sprayer)	**These values are the 75th percentiles for residents (assuming average breathing rates for inhalation exposures)**			
	Dermal (mL spray dilution/person)		**Inhalation (mL spray dilution/person)**	
	Adults	**Children**	**Adults**	**Children**
Arable/ground boom sprayer				
2 m	0.47	0.33	0.00010	0.00022
5 m	0.24	0.22	0.00009	0.00017
10 m	0.20	0.18	0.00009	0.00013
Orchard/broadcast air assisted applications [(a)]				
2–3 m	n.a.	n.a.	n.a.	n.a.
5 m	5.63	1.689	0.0021	0.00164
10 m	5.63	1.689	0.0021	0.00164

(a): The only available values are for the 8-m distance downwind from the middle of the tree trunk, which are assumed to represent a 5-m distance from the edge of the orchard; the same value is used for 5 and 10 m.

n.a., not available.

Table 17: Dermal and inhalation exposures for residents (mean data on potential dermal and inhalational exposures) (adapted and amended from EFSA PPR Panel, 2010)

Method of application (distance from sprayer)	These values are the mean values (assuming average breathing rates for inhalation exposures)			
	Dermal (mL spray dilution/person)		Inhalation (mL spray dilution/person)	
	Adults	Children	Adults	Children
Arable/ground boom sprayer				
2 m	0.22	0.18	0.00009	0.00017
5 m	0.12	0.12	0.00008	0.00014
10 m	0.11	0.10	0.00007	0.00011
Orchard/broadcast air assisted applications [(a)]				
2–3 m	n.a.	n.a.	n.a.	n.a.
5 m	3.68	1.11	0.00170	0.00130
10 m	3.68	1.11	0.00170	0.00130

(a): The only available values are for the 8-m distance downwind from the middle of the tree trunk, which are assumed to represent a 5-m distance from the edge of the orchard; the same value is used for 5 and 10 m.
n.a., not available.

It is noted that no data are available for manual application. The WoG proposes that the same data be used for manual application as for vehicle application as a first tier assessment (i.e. deposition values for broadcast air-assisted sprayers for upwards manual application, and field crop sprayer values for downwards manual application). Further refinement could be needed on a case-by-case basis.

The BREAM calculator provides dermal and inhalation exposure estimates from arable applications for adults and children. Based on the scenario above, the 75th percentile values in Table 16 are based on the following:

- dermal exposure: adults 0.47 mg and children 0.33 mg. Note, for these examples, 1 mg a.s. = 1 mL spray solution (concentration spray solution 1 g a.s./L; see Table 15)
- inhalation exposure: adults, breathing 0.575 m^3/h, 0.0001 mg; and children, breathing 0.45 m^3/h, 0.00022 mg.

Lloyd et al. (1987) provides values measured for orchard applications for adults only. The values for adults in Table 16 were re-calculated for children:

- dermal exposure = 5.63 mL × 0.3 (child/adult body area) = 1.689 mL
- inhalation exposure = 0.0021 mL × 0.45 m^3/h (child breathing rate) or 0.575 m^3/h (adult breathing rate) = 0.00164 mL.

The average values in Table 17 are derived from the corresponding data in the same manner.

Without additional data, no adjustment of data from Lloyd et al. (1987) for further distances is possible. However, drift-reducing nozzles can be considered as a risk mitigation measure. Corresponding safety instructions on the label are necessary. An adjustment of drift based on 50 % reducing nozzles was agreed by the WoG, considering 50 % as a reliable factor from experimental data showing from 50 to 90 % drift reduction (e.g. Guidelines for the testing of plant protection products Part VII, April 2000. Federal Biological Research Centre for Agriculture and Forestry Federal Republic of Germany). However, these tests are performed measuring drift up to a height of 50 cm only. Further drift measurements are required for implementation of drift-reducing nozzles considering > 50 % drift reduction.

6.3.1.2. Vapour

Exposures to vapour should be estimated using the method that has been developed in the UK (CRD, 2008) and Germany (Martin et al., 2008), based on the highest time-weighted average exposure for a 24-hour period, according to the volatility of the active substance:

$SER_I = (VC \times IR \times IA)/BW$

where:

- SER_I = systemic exposure of residents via the inhalation route (mg/kg bw per day)
- VC = vapour concentration (mg/m^3)
- IR = inhalation rate (m^3/day)
- IA = inhalation absorption (%)
- BW = body weight (kg).

For moderately volatile compounds (vapour pressure ≥ 0.005 Pa and < 0.01 Pa), exposures should be calculated assuming a default concentration in the air of 15 µg/m^3 and daily average breathing rates as reported in Table 3, resulting in:

- an adult value of 15 µg/m^3 × 0.23 m^3/day/kg × 60 kg = 3.45 µg/day/kg × 60 kg = 207 µg/day
- a child value of 15 µg/m^3 × 1.07 m^3/day/kg × 10 kg = 16.05 µg/day/kg × 10 kg = 160.5 µg/day.

For compounds with low volatility (vapour pressure < 0.005 Pa), exposures should be calculated assuming a default concentration in the air of 1 µg/m^3 and daily average breathing rates as reported in Table 4, resulting in:

- an adult value of 1 µg/m^3 × 0.23 m^3/day/kg × 60 kg = 0.23 µg/day/kg × 60 kg = 13.8 µg/day
- a child value of 1 µg/m^3 × 1.07 m^3/day/kg × 10 kg = 1.07 µg/day/kg × 10 kg = 10.7 µg/day.

Any future possibility of modifying the vapour pressure value and the concentration in the air will allow a refinement of the exposure calculations.

6.3.1.3. Surface deposits

Dermal exposure from surface deposits based on spray drift should be based on the following equation (EFSA PPR Panel, 2010):

$SER_D = (AR \times D \times TTR \times TC \times H \times DA)/BW$

where:

- SER_D = systemic exposure of residents via the dermal route (mg/kg bw/day)
- AR = application rate (mg/cm^2) (consider MAF, if necessary)
- D = drift (%) (if multiple applications have to be taken into account, a lower percentile could be considered for risk refinement)
- TTR = turf transferable residues (%) (for products applied in liquid sprays, 5 %, and for products applied as granules, 1 % (these values come from data obtained using the Modified Californian Roller Method (Fuller et al., 2001; Rosenheck et al., 2001) and represent the upper end of the range from a number of studies with different compounds))

- TC = transfer coefficient (cm^2/h) (default values of 7300 cm^2/h for adults and 2600 cm^2/h for children are recommended, TC values take into account minimal protection from clothes)
- H = exposure duration (hours) (a default value of two hours is recommended by US EPA, 2001)
- DA = dermal absorption (%)
- BW = body weight (kg).

Exposure from surface deposits for children aged less than three years should be calculated using the following equation:

Dermal exposure + hand to mouth transfer + object to mouth transfer

Children's hand to mouth transfer should be calculated using the following equation:

$SOE_H = (AR \times D \times TTR \times SE \times SA \times Freq \times H \times OA)/BW$

where:

- SOE_H = systemic oral exposure via the hand to mouth route (mg/kg bw/day)
- AR = application rate (mg/cm^2) (consider MAF, if necessary)
- D = drift (%) (if multiple applications have to be taken into account, a lower percentile could be considered for risk refinement)
- TTR = turf transferable residues (%) (for products applied in liquid sprays, 5 % is used, and, for products applied as granules, 1 % is used (these values come from data obtained using the Modified Californian Roller Method (Fuller et al., 2001; Rosenheck et al., 2001), and represent the upper end of the range from a number of studies with different compounds)
- SE = saliva extraction factor (%) (a default value of 50 % is recommended by US EPA, 2001; it refers to the fraction of pesticide extracted from a hand/object via saliva. It is a median value from a study by Camann and colleagues on the fraction of pesticide extracted by saliva from hands (Camann et al., 1995))
- SA = surface area of hands (cm^2) (the assumption used here is that 20 cm^2 of skin area is contacted each time a child puts a hand in his or her mouth (US EPA, 2001))
- Freq = frequency of hand to mouth (events per hour) (for short-term exposures, a value of 9.5 events per hour is recommended; this is the average of observations ranging from 0 to 70 events per hour (US EPA, 2001))
- H = exposure duration (hours) (a default value of two hours is recommended by US EPA, 2001)
- OA = oral absorption (%)
- BW = body weight (kg).

Children's object to mouth transfer should be calculated using the following equation:

$SOE_O = (AR \times D \times DRP \times IgR \times OA)/BW$

where:

- SOE_O = systemic oral exposure via the object to mouth route (mg/kg bw/day)
- AR = application rate (mg/cm^2) (consider MAF, if necessary)

- D = drift (%)
- DPR = dislodgeable residues percentage (%) (a default value of 20 % transferability for object to mouth assessments is recommended by US EPA, 2001)
- IgR = ingestion rate for mouthing of grass/day (cm^2) (a default value of 25 cm^2 of grass/day is recommended by US EPA, 2001)
- OA = oral absorption (%)
- BW = body weight (kg).

Values for drift percentage should be taken from Table 18, as appropriate.

Different risk mitigation measures for the assessment of surface deposits can be applied. For example, safety distances of > 2 or > 3 m can be used for the risk assessment. Furthermore, drift-reducing nozzles of 50 % can be considered as a risk mitigation measure in this Guidance (see for example Guidelines for the testing of plant protection products Part VII, April 2000. Federal Biological Research Centre for Agriculture and Forestry Federal Republic of Germany). Corresponding safety instructions on the label are necessary. Any further risk mitigation measures need to be supported by data (including an assessment of the conditions used to derive the proposed measures compared with the conditions used to estimate the drift values proposed in this Guidance).

Table 18: Ground sediments based on drift as a percentage of the application rate

Distance	**Field crops (%)** [(a)]		**Fruit crops, early stages** [(b)]		**Fruit crops, late stages** [(b)]		**Grapes** [(b)]		**Hops** [(b)]	
	Mean	P75	Median	P77	Median	P77	Median	P77	Median	P77
2–3 m	4.1	5.6	18.96	23.96	6.96	11.01	5.25	6.90	9.95	15.93
5 m	1.8	2.3	11.69	15.79	3.73	6.04	2.32	3.07	5.91	8.57
10 m	1.0	1.3	6.07	8.96	1.6	2.67	0.77	1.02	2.91	3.70

(a): From BREAM.
(b): From Ganzelmeier/Rautmann (the 75^{th} percentile is not published).
P75, 75^{th} percentile; P77, 77^{th} percentile.

Based on the limited availability of data, for products applied as granules, drift from applications of granules should be assumed to be 3 % for broadcast and manual applications. Further refinements could be considered based on new data. Dust drift for in-furrow applications are considered to be negligible.

6.3.1.4. Entry into treated crops

Entry into treated crops is based on exposure from activities such as walking in treated fields for adults.

The method used should be the same as for workers, with the same DFR and a TC based on data for inspection activities (75^{th} percentile: 7500 cm^2/h, mean: 5980 cm^2/h) , and with a 15-minute exposure. TC values are only available for adults. A factor of 0.3 has been applied to the adult TC for children re-entering treated crops.

For entry onto treated lawns (two hours of inhalation), exposures should be calculated in the same way as surface deposits (see above), but using a deposition percentage of 100 %. For children, all the pathways of exposure to surface deposits are relevant. Currently, for adults, object to mouth and hand to mouth transfer of surface deposits are considered less important and are not considered in the exposure calculator.

For turf treatments, the calculation of exposure to drift fallout is not relevant when bystanders/residents are exposed when entering treated areas directly; the exposure calculation should consider a 100 % surface deposit for people entering treated lawns directly.

6.3.2. Bystander exposure

Exposures for bystanders should be assessed in the same way as for residents, except that dermal and inhalation exposures to spray drift should be taken as the 95th percentile values derived from the underpinning datasets. However, the four estimated exposures will be kept separated because, based on the available data, the WoG considers that it is unlikely and unrealistic that all the different exposures from the different pathways will occur contemporaneously in the case of bystanders using a probability of 95 %.

For surface deposits, the transfer coefficients should be replaced with 14 500 cm^2/h for adults and 5 200 cm^2/h for children (short-term exposure of 15 minutes, recommended by US EPA 2001), and the frequency of infant hand to mouth activity should be 20 events per hour (95th percentile of the range of values from 0 to 70).

6.3.2.1. Spray drift

The exposures from spray drift should be calculated using the following equation:

Dermal exposure × dermal absorption percentage + inhalation exposure

where the dermal absorption percentage is that for the in-use dilution taken from the toxicological evaluation, and dermal and inhalation exposures are those shown in Table 19.

Table 19: Dermal and inhalation exposures for bystanders (95th percentile) (adapted and amended from EFSA PPR Panel, 2010)

Method of application/distance from sprayer	95th percentiles for bystanders (assuming high breathing rates for inhalation exposures)			
	Dermal (mL spray dilution/person)		Inhalation (mL spray dilution/person)	
	Adults	Children	Adults	Children
Arable/ground boom sprayer				
2 m	1.21	0.74	0.00050	0.00112
5 m	0.57	0.48	0.00048	0.00083
10 m	0.48	0.39	0.00051	0.00076
Orchard/broadcast air assisted applications (a)				
2–3 m	n.a.	n.a.	n.a.	n.a.
5 m	12.9	3.87	0.0044	0.0035
10 m	12.9	3.87	0.0044	0.0035

(a): The only available values are for the 8-m distance downwind from the middle of the tree trunk, which are assumed to represent a 5-m distance from the edge of the orchard; the same value is used for 5 and 10 m.
n.a., not available.

Using the BREAM calculator, the values for arable crops in Table 19 should be based on the following:

- dermal exposure: adults 1.21 mg (10 kg) and children 0.74 mg (for this example, mg = mL)
- inhalation exposure: adults at 2.4 m^3/h 0.0005 mg and children at 1.9 m^3/h 0.00112 mg (for this specific example 1 mg a.s. = 1 mL spray solution).

For orchard applications, Lloyd et al. (1987) provide 95th percentile exposures: dermal, 12.9 mL (maximum), and inhalation, 0.0044 mL. These figures are for adults. Assuming that the vertical spray drift profile is uniform for both adult and child heights, child values can be estimated as follows:

- dermal = 12.9 mL × 0.3 (child/adult body area) = 3.87 mL
- inhalation = 0.004 mL × (1.9 child/2.4 adult) = 0.0035 mL.

6.3.2.2. Vapour

Exposures to vapour should be calculated in the same way as for residents (see section 6.3.1.2).

6.3.2.3. Surface deposits

Dermal exposures from surface deposits based on spray drift should be based on the following equation (EFSA PPR Panel, 2010):

$$SEB_D = (AR \times D \times TTR \times TC \times H \times DA)/BW$$

where:

- SER_D = systemic exposure of bystander via the dermal route (mg/kg bw/day)
- AR = application rate (mg/cm^2) (consider MAF, if necessary)
- D = drift (%) (if multiple applications have to be taken into account, a lower percentile could be considered for risk refinement)
- TTR = turf transferable residues (%) (for products applied in liquid sprays, 5 % is used, and, for products applied as granules, 1 % is used. These values come from data obtained using the Modified Californian Roller Method (Fuller et al., 2001; Rosenheck et al., 2001), and represent the upper end of the range from a number of studies with different compounds
- TC = transfer coefficient (cm^2/h) (default values of 14 500 cm^2/h for adults and 5 200 cm^2/h for children are recommended; TC values take into account minimal protection from clothes)
- H = exposure duration (hours) (a default value of two hours to cover resident exposure)
- DA = dermal absorption (%)
- BW = body weight (kg).

Exposure from surface deposits for children less than three years old should be calculated using the following equation:

Dermal exposure + hand to mouth transfer + object to mouth transfer

Children's hand to mouth transfer should be calculated using the following equation:

$$SOE_H = (AR \times D \times TTR \times SE \times SA \times Freq \times H \times OA)/BW$$

where:

- SOE_H = systemic oral exposure via the hand to mouth route (mg/kg bw/day)
- AR = application rate (mg/cm^2) (consider MAF, if necessary)
- D = drift (%) (if multiple applications have to be taken into account, a lower percentile could be considered for risk refinement)
- TTR = turf transferable residues (%) (for products applied in liquid sprays, 5 % is used, and, for products applied as granules, 1 % is used. These values come from data obtained using the Modified Californian Roller Method (Fuller et al., 2001; Rosenheck et al., 2001), and represent the upper end of the range from a number of studies with different compounds

- SE = saliva extraction factor (%) (a default value of 50 % is recommended by US EPA, 2001; it refers to the fraction of pesticide extracted from a hand/object via saliva. It is a median value from a study by Camann and colleagues on the fraction of pesticide extracted by saliva from hands (Camann et al., 1995))
- SA = surface area of hands (cm^2) (the assumption used here is that 20 cm^2 of skin area is contacted each time a child puts a hand in his or her mouth (US EPA, 2001))
- Freq = frequency of hand to mouth (events per hour) (for short-term exposures, the value of 20 events per hour is recommended; this is the 95^{th} percentile of observations ranging from 0 to 70 events per hour (US EPA, 2001))
- H = exposure duration (hours) (a default value of two hours to cover resident exposure)
- OA = oral absorption (%)
- BW = body weight (kg).

Children's object to mouth transfer should be calculated using the following equation:

$SOE_O = (AR \times D \times DRP \times IgR \times OA)/BW$

where:

- SOE_O = systemic oral exposure via the object to mouth route (mg/kg bw/day)
- AR = application rate (mg/cm^2) (consider MAF, if necessary)
- D = drift (%)
- DRP = dislodgeable residues percentage (%) (a default value of 20 % transferability for object to mouth assessments is recommended by US EPA, 2001)
- IgR = ingestion rate for mouthing of grass/day (cm^2) (a default value of 25 cm^2 of grass/day is recommended by US EPA, 2001)
- OA = oral absorption (%)
- BW = body weight (kg).

Values for drift percentage should be taken from Table 20, as appropriate.

Different risk mitigation measures for the assessment of surface deposits can be applied at the Member State level. For example, safety distances of > 2 or 3 m can be used for the risk assessment. Furthermore, drift-reducing nozzles of 50 % can be considered as a risk mitigation measure in this Guidance (see Guidelines for the testing of plant protection products Part VII, April 2000. Federal Biological Research Centre for Agriculture and Forestry Federal Republic of Germany). Corresponding safety instructions on the label are necessary. Any further risk mitigation measures need to be supported by data (including an assessment of the conditions used to derive the proposed measures compared with the conditions used to estimate the drift values proposed in this Guidance).

Table 20: Ground sediments as a percentage of the application rate, calculated on the basis of the 95th/90th percentile values

Distance	Field crops [(a)] 95th percentile	Fruit crops, early stages [(b)] 90th percentile	Fruit crops, late stages [(b)] 90th percentile	Grapes [(b)] 90th percentile	Hops [(b)] 90th percentile
2–3 m	8.5 %	29.20	15.73	8.02	19.33
5 m	3.5 %	19.89	8.41	3.62	11.57
10 m	1.9 %	11.81	3.60	1.23	5.77

(a): From BREAM.
(b): From Ganzelmeier/Rautmann.

Drift from agricultural applications of granules (general granule application, e.g. slug pellets) is assumed to be 3 % for broadcast and manual applications ("worst case"). Dust drift for in-furrow applications is considered to be negligible.

6.3.2.4. Entry into treated crops

For entry into crops, refer to section 6.3.1.4.

For entry onto treated lawns, exposures should be calculated in the same way as for surface deposits (see above), but using a deposit (% of application rate) of 100 %.

When estimating the maximum exposure that a bystander might reasonably be expected to incur in a single day by higher tier methods, account must be taken of the possibility that a bystander could be a resident.

CONCLUSIONS

The peer review of all available data for the assessment of the exposure of the operator, worker, resident and bystander to PPPs, as reported in the EFSA PPR Panel opinion (EFSA PPR Panel, 2010), represented the starting point for the preparation of this GD. EFSA undertook actions to collect data to fill the gaps highlighted in the PPR Panel opinion (EFSA PPR Panel, 2010) and some new data were made available.

It is the opinion of the WoG that this Guidance represents a huge step forward for the harmonisation of the pesticide exposure assessment for operators, workers, residents and bystanders at the EU level. However, many gaps still remain and are highlighted.

Further actions are therefore needed to increase the representativeness of the assessments proposed.

RECOMMENDATIONS

The Guidance should hereafter be reviewed periodically, as and when relevant new data become available, and, if appropriate, should be amended or revised.

The WoG highlights the following specific data gaps:

- Operator
  - Seed treatment exposure scenarios, greenhouse exposure scenarios, home and allotment garden exposure scenarios and other minor scenarios are not covered by the Guidance.
  - The possibility of using water-soluble bags was considered; exposure to PPPs during mixing and loading is likely to be limited but not negligible. Based on expert judgement and approaches at the national level, the WoG decided that the exposure deriving from ML activities of water-soluble bags is assumed to be 10 % of the corresponding

formulation (the option is not included in the exposure calculator). However, the WoG recommends that further data are made available to refine the proposed value.

- In the commenting phase it was indicated that students or migrant workers might be used by farmers for either applying PPPs or in re-entry activities: EFSA was asked to include in the exposure calculator a scenario with less experienced people who were not used to protecting themselves and had little knowledge of the toxicity of the pesticides; however, no data are available to model these cases. In addition, operators and workers have to be trained based on the risk assessment of their workplace.

- Use of PPE
    - The WoG made use of available data in order to reach a better refined and harmonised exposure assessment with the use of PPE. However, the WoG points out that a lot still needs to be done for an appropriate application of the proposed factors at the post-marketing level.
- Workers
    - Available data are not reliable enough to proceed with the acute exposure assessment (in particular with regard to the TC and DFR values). The WoG strongly recommends further collection/production of data on specific TC and DFR values to produce more realistic exposure assessments.
- Residents and bystanders
    - Few data are available to establish the impact of single exposure routes on the overall exposure assessment. The WoG covered the main pathways. Further qualitative and quantitative information on the different pathways of resident and bystander exposure is strongly recommended to perform a more realistic exposure assessment. In addition, the WoG recommends further collection/production of data on exposure pathways, other than the ones considered, in order to produce more realistic exposure assessments.
    - The WoG recommends to further collect/produce data on relevant drift for residents/bystanders after application in high crops.
    - The WoG recommends to further collect/produce data on relevant daily air concentrations (based on vapour pressure) of substances.
    - The WoG recommends further collection/production of data on the specific geography and topography of an area and specific weather conditions to produce more realistic scenarios.
    - The US EPA values proposed in the 2012 Standard Operation Procedure for Residential Exposure Assessment need to be carefully considered before they can be put into the current context proposed in the GD. The WoG strongly recommends this is done in a comprehensive way for the resident and bystander exposure assessment.
    - No reference is made to exposure from dust drift from sowing of treated seeds. This is because of a lack of data; however, during the public consultation, the WoG was informed that data are available at the Member State level. A recommendation is made for bringing together all of these studies and analysing the possibility of modelling this scenario.
    - Regarding the exposure of people eating from their own gardens where drift has occurred, and where a pre-harvest interval is not respected, this should be considered under the dietary risk assessment (outside the scope of the GD). The issue is highlighted for future assessment.

- General
  - The need for an aggregate exposure assessment was indicated in the comments during the public consultation of the draft GD. It is noted that a methodology is currently under development in the EU.
  - In order to perform an appropriate risk assessment, in the PPR Panel opinion (2010), reference was made to the need for an Acute Acceptable Operator Exposure Level for active substances with the potential to induce acute systemic toxicity. Although this was still present in the draft Guidance circulated for public consultation, the WoG decided to remove the concept from the final version of the Guidance, indicating instead that the risk assessment should be performed using the most appropriate reference values. This decision was taken after consideration of the comments received and the lack of an appropriate methodology to derive such a reference value. The WoG recommends that actions are taken to support the risk assessors in this activity.

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APPENDICES

Appendix A. Cipac formulation codes

(Catalogue of pesticide formulation types and international coding system, Technical Monograph No 2, 6th Edition, CropLife International.)

AE	Aerosol dispenser	***MC***	Mosquito coil
AL	Other liquids to applied undiluted	***ME***	Microemulsion
AP	All other products to be applied undiluted	***OD***	Oil dispersion
BR	Briquette	***OF***	Oil miscible flowable concentrate (oil miscible suspension)
CB	Bait concentrate	***OL***	Oil miscible liquid
CP	Contact powder	***OP***	Oil dispersible powder
CS	Capsule suspension	***PA***	Paste
DC	Dispersible concentrate	***PR***	Plant rodlet
DP	Dustable powder	***PS***	Seed coated with a pesticide
DS	Powder for dry seed treatment	***RB***	Bait (ready fore use)
DT	Tablets for direct application	***SC***	Suspension concentrate (= flowable concentrate)
EC	Emulsifiable concentrate	***SD***	Suspension concentrate for direct application
EG	Emulsifiable granule	***SE***	Suspo-emulsion
EO	Emulsion, water in oil	***SG***	Water-soluble granule
EP	Emulsifiable powder	***SL***	Soluble concentrate
ES	Emulsion for seed treatment	***SO***	Spreading oil
EW	Emulsion, oil in water	***SP***	Water-soluble powder
FS	Flowable concentrate for seed treatment	***ST***	Water-soluble tablets
FU	Smoke generator	***SU***	Ultralow volume (ULV) suspension
GA	Gas	***TB***	Tablet
GE	Gas generating product	***TC***	Technical material
GL	Emulsifiable gel	***TK***	Technical concentrate
GR	Granule	***UL***	Ultra-low volume (ULV) liquid
GS	Grease	***VP***	Vapour releasing product
GW	Water-soluble gel	***WG***	Water dispersible granule
HN	Hot fogging concentrate	***WP***	Wettable powder
KK	Combi-pack solid/liquid	***WS***	Water dispersible powder for slurry treatment
KL	Combi-pack liquid/liquid	***WT***	Water dispersible tablets
KN	Cold fogging concentrate	***XX***	Others
KP	Combi-pack solid/solid	***ZC***	A mixed formulation of CS and SC
LN	Long-lasting insecticidal net	***ZE***	A mixed formulation of CS and SE
LS	Solution for seed treatment	***ZW***	A mixed formulation of CS and EW

For record keeping purposes, the suffix “SB” should be added to the formulation code if the material is packaged in a sealed water-soluble bag (e.g. WP–SB).

“FG” (fine granules) is not reported in the table.

Appendix B. Multiple application factor (MAF)

Multiple applications of a compound may cause a build-up of residue levels and must be taken into account in the exposure assessment for the estimated theoretical exposure (ETE) equation. As long as only peak concentrations are considered in the risk assessment, residue dynamics can be expressed by a MAF. The MAF is a function of the number of applications, the application interval and the decline of residues, typically expressed as a DT_{50} assuming first order kinetics (single first order ($SFO\text{-}DT_{50}$)). Equation is presented below for the calculation of a MAF for average residue levels (MAFm).

(GD on birds and mammals, available online: http://www.efsa.europa.eu/en/efsajournal/pub/1438.htm)

In the calculation of the MAF, the build-up of residues is expressed by the number of applications (n). A MAFm factor, for use with average mean residue unit doses data, is calculated using the following equation:

$$MAF_m = \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

where:

$k = \ln(2)/DT_{50}$ (rate constant)

n = number of applications

i = application interval (d)

By forming the limit value, $\lim n \rightarrow \infty$, of the equation above, the term e^{-nki} becomes zero and a "plateau" MAFm for an infinite number of applications can be calculated.

Appendix C. DT50 (days required for 50 % dissipation of the initial concentration) values for pesticide active substances on foliage (from Willis and McDowell, 1987)

Active substance	DT50	Active substance	DT50	Active substance	DT50
2,4-D	3.0	Endosulfan (EC)	1.0	Methomyl (EC)	0.4
2,4-D	2.4	Endosulfan (EC)	4.7	Methomyl (liquid)	0.5
2,4-D	1.1	Endosulfan (WP)	4.9	Methomyl (liquid)	0.5
Acephate (SP)	1.7	Endosulfan (WP)	3.6	Methomyl (liquid)	0.7
Acephate (SP)	8.2	Endrin (D)	1.0	Methomyl (ULV oil)	0.7
Aldrin (EC) [(a)]	1.7	EPN	7.0	Methomyl (WP)	1.7
Avermecin B_1	1.5	EPN (EC)	1.4	Methomyl (WP)	0.8
Azinphos-methyl	2.0	EPN (EC)	1.1	Methomyl (WP)	1.2
Benomyl (WP)	6.0	EPN (EC)	0.8	Methoxychlor (WP)	6.3
Benomyl (WP)	7.2	EPN (ULV oil)	0.6	Methylparathion	1.0
Carbaryl	1.4	Ethion (EC)	7.9	Methylparathion (E)	13.0
Carbaryl (EC)	1.2	Ethion (WP)	5.8	Methylparathion (E)	2.9
Carbaryl (liquid)	29.5	Ethion (WP)	17.0	Methylparathion (E)	2.0
Carbaryl (WP)	25.4	Ethyl parathion	1.6	Methylparathion (E)	1.2
Carbaryl (WP)	7.4	Ethyl parathion (EC)	0.7	Methylparathion (EC)	0.5
Carbaryl (WP) [(b)]	1.3	Ethyl parathion (EC)	0.7	Methylparathion (EC)	0.5
Carbaryl (XLR)	1.5	Ethyl parathion (EC)	1.0	Methylparathion (EC)	0.5
Carbofuran	3.2	Ethyl parathion (EC)	6.9	Methylparathion (EC)	0.4
Carbofuran (EC)	1.1	Ethyl parathion (WP)	1.5	Methylparathion (EC)	0.1
Carbophenothion (EC)	7.0	Ethyl parathion (WP)	4.4	Methylparathion (EC)	1.1
Carbosulfan (EC)	2.4	Ethyl parathion (WP)	1.2	Methylparathion (EC)	0.6
Chlordane (WP)	2.3	Ethyl parathion (WP)	1.8	Methylparathion (EC)	1.0
Chlordimeform (EC) [(a)]	0.7	Ethyl parathion (WP)	3.3	Methylparathion (EC)	1.6
Chlorpyrifos (EC)	0.7	Fenitrothion (EC)	2.6	Methylparathion (EC)	0.6
DDT (EC)	1.6	Fensulfothion (EC)	2.7	Methylparathion (ULV)	0.6
DDT (EC)	9.5	Fensulfothion (EC)	3.3	Monocrotophos	3.1
Deltamethrin	7.7	Fenthion (EC)	2.4	Monocrotophos (EC)	3.4
Demeton	8.8	Fenvalerate (EC)	9.5	Monocrotophos (WM)	1.3
Dialifor	17.0	Heptachlor	1.7	Oxamyl (EC)	0.7
Diazinon (E)	2.5	Malathion (D)	0.8	Permethrin (EC)	3.0
Diazinon (EC)	1.2	Malathion (D)	1.0	Permethrin (WP)	4.9
Diazinon (EC)	0.7	Malathion (D)	1.4	Phenthoate	1.5
Diazinon (WP)	0.8	Malathion (D)	2.9	Phenthoate	3.1
Dieldrin	2.7	Malathion (EC)	0.7	Phenthoate	3.6
Dieldrin (D)	4.2	Malathion (EC)	1.7	Phorate (EC)	1.4
Dieldrin (EC)	6.8	Malathion (EC)	6.8	Phosmet (WP)	3.2
Diflubenzuron (WP)	25.0	Malathion (WP)	1.4	Phosphamidon	4.0
Dimethoate	2.5	Malathion (WP)	1.5	Phoxim (EC)	1.5
Dimethoate (EC)	2.2	Malathion (WP)	5.8	Phoxim (EC)	2.1
Dimethoate (LC)	3.1	Methamidophos	1.7	Profenofos (EC)	1.2
Dimethoate (LC)	2.7	Methidathion (EC)	0.5	Sulprofos (EC)	0.8
Dimethoate (LC)	0.9	Methidathion (ULV oil)	0.6	Sulprofos (ULV oil)	0.6
Endosulfan	2.9	Methomyl	2.5	Toxaphene (EC)	1.6

2,4-D, 2,4-Dichlorophenoxyacetic acid; D, dust; DDT, dichlorodiphenyltricholoethane; E, emulsion; EC, emulsifiable concentrate; EPN, *O*-Ethyl *O*-(4-nitrophenyl) phenylphosphonothioate; LC, liquid concentrate; SP, water-soluble powder; ULV, ultra-low volume; WP, wettable powder.

The Willis and McDowell dataset reports 130 half-life values for 48 compounds. These data indicate whether the values are for total or dislodgeable residues. There are 76 values for dislodgeable residues and the longest half-life is 25 days for diflubenzuron. There are 46 values for total residues and the longest half-life here is 29.5 days for carbaryl. For carbaryl, there are also data for dislodgeable residues where the half-life values are much shorter, but, for other compounds, the variability in data is such that the total residue values are sometimes shorter than the dislodgeable residue half-life value.

Appendix D. Half-life values (USDA ARS pesticides properties database)

The United States Department of Agriculture (USDA) Agricultural Research Service (ARS) dataset reported foliar half-life (expressed in days) values for 277 compounds. Excluding arsenic, about 13 % of these had values reported as 30 days or more (i.e. one of 37 and one of 60).

AI Name	Foliar half-life
2-(m-Chlorophenoxy)propionamide	3
2,4,5-Trichlorophenoxyacetic acid, triethylamine salt	10
2,4-D, dimethylamine salt	9
2,4-DB, ester	9
2,4-DB, dimethylamine salt	9
2,4-Dichlorophenoxyacetic acid	5
Acephate (ANSI)	3
Alachlor (ANSI)	3
Aldrin	2
Ametryn (ANSI)	5
Amidochlor (ANSI)	8
Aminocarb	4
Amitraz (ANSI)	1
Amitrole (ANSI)	5
Ancymidol (ANSI)	30
Anilazine	1
Arsenic acid	10 000
Atrazine (ANSI)	5
Azinphos-methyl	2
Azoxystrobin (BSI, ISO)	3
Bendiocarb (ANSI)	3
Benfluralin	10
Benomyl (ANSI)	6
Bensulide	30
Benzene hexachloride, all isomers	3
Bifenox (ANSI)	3
Bifenthrin (ANSI)	7
Bromacil (ANSI)	20
Bromoxynil (ANSI)	3
Bromoxynil octanoate	3
Butoxyethyl triclopyr	15
Butralin (ANSI)	10
Butylate	1
Cacodylic acid, sodium salt	7
Captan (ANSI)	9
Carbaryl (ANSI)	7
Carbofuran (ANSI)	2
Carbophenothion (ANSI)	6
Chinomethionate	10
Chloramben (ANSI)	7
Chloramben, ammonium salt	7
Chloramben, sodium salt	7
Chlordane	3
Chlordimeform (ANSI)	1
Chlordimeform hydrochloride	1
Chlorfenac	30
Chlorimuron-ethyl	15
Chlorobenzilate	10
Chloroneb (ANSI)	30

AI Name	Foliar half-life
Chlorophacinone	3
Chlorothalonil (ANSI)	10
Chloroxuron (ANSI)	15
Chlorpropham	8
Chlorpyrifos (ANSI)	3
Chlorsulfuron (ANSI)	30
Chlorthal-dimethyl	10
Clethodim (ANSI)	7
Clomazone (ANSI)	3
Clopyralid (ANSI)	2
Copper sulfate	7
Coumaphos	3
Cyanazine	5
Cycloate	2
Cyfluthrin	5
Cypermethrin	5
Cyproconazole	3
Cyromazine (ANSI)	30
Dalapon, sodium salt	37
Daminozide (ANSI)	4
DDT	4
Deltamethrin	3
Desmedipham (ANSI)	5
Diazinon (ANSI)	4
Dicamba (ANSI)	9
Dichlobenil (ANSI)	5
Dichlorprop	9
Dichlorprop, butoxyethanol ester	9
Diclofop-methyl	8
Dicloran	4
Dicofol	4
Dicrotophos	20
Dieldrin	5
Diethatyl-ethyl	10
Difenzoquat (ANSI)	30
Difenzoquat methyl sulfate	30
Diflubenzuron (ANSI)	27
Dimethipin (ANSI)	3
Dimethoate (ANSI)	3
Dinocap	8
Dinoseb (ANSI)	10
Dinoseb ammonium salt	10
Diphenamid (ANSI)	5
Dipotassium endothall	7
Dipropetryn (ANSI)	5
Diquat dibromide	30
Disulfoton	3
Dithiopyr (ANSI)	3
Diuron (ANSI)	30
DNOC	8

AI Name	Foliar half-life
DNOC, sodium salt	8
Dodine (ANSI)	10
DSMA	30
d-trans-beta Cypermethrin	8
Endosulfan (ANSI)	3
Endothall (ANSI)	7
EPN	5
EPTC	3
Esfenvalerate	8
Ethalfluralin (ANSI)	4
Ethephon (ANSI)	5
Ethion (ANSI)	7
Ethofumesate (ANSI)	10
Ethyl 1-naphthaleneacetate	5
Etridiazole	3
Fenarimol (ANSI)	30
Fenbuconazole (ANSI)	3
Fenbutatin-oxide	30
Fenitrothion	3
Fenoxaprop-ethyl	5
Fensulfothion	3
Fenthion	2
Fentin hydroxide	18
Fenvalerate	10
Ferbam	3
Fipronil	3
Fluazifop-p-butyl	4
Flucythrinate (ANSI)	5
Flumetralin	7
Fluometuron (ANSI)	30
Flutolanil	3
Fluvalinate (ANSI)	7
Fomesafen sodium	30
Fonofos	3
Formetanate hydrochloride	30
Fosamine ammonium	4
Fosetyl-Al	0.1
Glufosinate-ammonium	4
Glyphosate (ANSI)	3
Glyphosate, isopropylamine salt	3
Hexaflumuron (ANSI)	3
Hexazinone (ANSI)	30
Hexythiazox	5
Imazamethabenz-methyl	18
Imazamox	3
Imazapyr (ANSI)	30
Imazapyr, isopropylamine salt	30
Imazaquin, monoammonium salt	20
Imazaquin, sodium salt	20
Imazethapyr (ANSI)	30
Imidacloprid	3
Iprodione (ANSI)	5
Isazofos (ANSI)	5
Isofenphos	30
Isoxaflutole	3
Lactofen (ANSI)	2

AI Name	Foliar half-life
Lambda-cyhalothrin	5
Lindane	3
Linuron (ANSI)	15
Malathion (ANSI)	3
Maleic hydrazide	10
Mancozeb	10
Maneb	3
MCPA	8
MCPA, dimethylamine salt	7
MCPB	7
Mecoprop	10
Mepiquat chloride	60
Merphos	7
Metalaxyl (ANSI)	30
Methamidophos (ANSI)	4
Methazole (ANSI)	5
Methidathion (ANSI)	3
Methiocarb	10
Methomyl (ANSI)	1
Methoxychlor	6
Methyl 2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-p-toluate	18
Methyl 6-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-m-toluate	18
Methyl nonyl ketone	3
Methyl parathion	3
Metiram	7
Metolachlor (ANSI)	5
Metribuzin	5
Metsulfuron-methyl	30
Mevinphos	1
Monocrotophos	2
MSMA	30
NAD	5
Naled (ANSI)	1
Napropamide	15
Naptalam	7
Naptalam, sodium salt	7
Norflurazon (ANSI)	15
Oryzalin (ANSI)	5
Oxadiazon (ANSI)	20
Oxamyl (ANSI)	4
Oxycarboxin (ANSI)	10
Oxydemeton-methyl	3
Oxyfluorfen (ANSI)	8
Paraquat dichloride	30
Parathion (ANSI)	4
Pebulate	4
Pendimethalin (ANSI)	30
Pentachloronitrobenzene	4
Permethrin, mixed cis,trans (ANSI)	8
Phenmedipham	5
Phenthoate	2
Phorate (ANSI)	2
Phosalone (ANSI)	8
Phosmet	3

AI Name	Foliar half-life
Phosphamidon (ANSI)	5
Phostebupirim	3
Picloram (ANSI)	8
Picloram, potassium salt	8
Picloram, triisopropanolamine salt	8
Piperalin	10
Prallethrin	3
Prochloraz (ANSI)	30
Profenofos (ANSI)	3
Profluralin (ANSI)	1
Prometon (ANSI)	30
Prometryn (ANSI)	10
Propachlor	3
Propamocarb hydrochloride	15
Propanil	1
Propargite (ANSI)	5
Propazine (ANSI)	5
Propham	2
Propiconazole	30
Propyzamide	20
Prosulfuron	3
Pyrazon (ANSI)	5
Pyridaben (proposed)	3
Pyridate	3
Pyrithiobac-sodium (ANSI proposed common name)	3
Quinclorac	3
Quizalofop-ethyl	15
Rimsulfuron (ANSI)	3
Sethoxydim	3
Siduron (ANSI)	30
Silvex (ANSI)	5
Simazine (ANSI)	5
Sodium acifluorfen	5

AI Name	Foliar half-life
Sodium asulam	3
Sodium bentazon	2
Sulfentrazone (ANSI)	3
Sulfometuron-methyl	10
Sulprofos	1
Tebufenozide (ANSI)	3
Tebuthiuron (ANSI)	30
Temephos (ANSI)	5
Terbacil (ANSI)	30
Terbufos (ANSI)	3
Terbutryn (ANSI)	5
Tetramethrin (ANSI)	3
Thiabendazole	30
Thidiazuron (ANSI)	3
Thifensulfuron-methyl	3
Thiobencarb (ANSI)	7
Thiodicarb (ANSI)	4
Thiophanate-methyl (ANSI)	5
Thiram	8
Toxaphene	2
Tralomethrin (ANSI)	1
Triadimefon	8
Triallate	15
Tribuphos	7
Trichlorfon	3
Tridiphane (ANSI)	8
Triethylamine triclopyr	15
Triflumizole	3
Trifluralin (ANSI)	3
Triflusulfuron-methyl	3
Triforine (ANSI)	5
Uniconazole (ANSI)	3
Vernolate	2

2,4-D, 2,4-dichlorophenoxyacetic acid; 2,4-DB, 4-(2,4-dichlorophenoxy)butyric acid; AI, active ingredient; ANSI, American National Standards Institute; BSI, British Standards Institution; DDT, dichlorodiphenyltricholoethane; DNOC, dinitro-*ortho*-cresol; DSMA, dimercaptosuccinic acid; EPN, *O*-ethyl *O*-(4-nitrophenyl) phenylphosphonothioate; EPTC, *S*-ethyl dipropylthiocarbamate; HL, half-life; ISO, International Organization for Standardization; MCPA, 2-methyl-4-chlorophenoxyacetic acid; MCPB, 4-(4-chloro-2-methylphenoxy)butanoic acid; MSMA, monosodium methyl arsenate; NAD, nicotinamide adenine dinucleotide.

Appendix E. Exposure calculation spreadsheet

Available at:

http://www.efsa.europa.eu/en/efsajournal/doc/3874ax1.zip

Appendix F. Exposure to soil-borne residues occurs in the absence of contact with treated foliage

For situations in which exposure to soil-borne residues occurs in the absence of contact with treated foliage, an estimate of potential (dermal) exposure may be derived by considering the concentration in the treated soil, together with soil dermal adherence data. As a default, the hand soil loading for a worker should be taken as 0.44 mg/cm^2 (EFSA, 2007). A default value for inhalation exposure should be estimated assuming a total inhalation dust exposure of 98.6 mg/m^3 EFSA, 2007).

For handling compost after admixture treatment, the concentration in compost should be derived from the label-recommended application rate for the admixture of the product with compost.

For other situations, soil concentration values should be sought from the fate and behaviour evaluation:

- for acute assessment, the highest initial predicted environmental concentrations (PEC) soil value should be used;
- if chronic exposure is a concern, an appropriate time-weighted average (TWA) value may be used.

Where values are not available from the fate and behaviour evaluation, soil concentrations for field applications can be estimated assuming:

- the distribution is limited to the top 5 cm layer, or 20 cm when cultivation follows the application;
- soil density is 1.5 g/cm^3; and
- 100 % (worst-case PEC soil) of the applied dose reaches the soil surface (where ground cover is present, a minimum of 50 % of the applied dose reaches the soil surface).

Appendix G. Comparison of transfer coefficient values used in the Guidance with US EPA

Crop	Nature of task	Main body parts in contact with foliage	TC (cm^2/h), total potential exposure	TC (cm^2/h) assuming arm, body and legs covered (bare hands)	TC (cm^2/h), covered body and gloves	Applicable to the following crops	EUROPOEM II details	Actual EUROPOEM value used in exposure calculator	US EPA—TC	Task details
Vegetables	Reach/pick	Hand and body	5 800	2 500	580	Brassica vegetables	75^{th} = 2 200 cm^2/h hands	2 500	4 200	Hand harvesting
						Fruiting vegetables	75^{th} = 3 600 cm^2/h body	2 500	1 100	Hand harvesting (peppers, tomato)
						Leaf vegetables and fresh herbs	Hands and body = 5 800 cm^2/h	2 500	1 400	Hand harvesting
						Legume vegetables	10-fold reduction for protective clothing	2 500	1 100	Hand harvesting
						Bulb vegetables	Total = 2 560 cm^2/h approx. 2 500 With gloves same method = 580 cm^2/h (own calculation)	2 500	4 200	Hand weeding
Tree fruits	Search/reach/pick	Hand and body	22 500	4 500	2 250	Citrus	75^{th} = 2 500 cm^2/h hands	4 500	1 400	Hand harvesting
						Cane fruits	75^{th} = 10 000 cm^2/h body 90^{th} = 20 000 cm^2/h body	4 500	1 400	Hand harvesting
						Oilfruits	Hands and body = 22 500 cm^2/h (90^{th} for body as the database is small)	4 500	1 400	Hand harvesting
						Pome fruits	Total = 4 500 cm^2/h approx. 4 500	4 500	3 600	Thinning fruit
						Stone fruits	With gloves same method = 2 250 cm^2/h (own calculation)	4 500	3 600	Thinning fruit
						Tree nuts		4 500	1 400	Hand harvesting
Grapes	Harvesting	Hand and body	30 000	10 100	No justified proposal possible				10 100	Hand harvesting (19 300 harvesting, mechanically assisted)

Crop	Nature of task	Main body parts in contact with foliage	TC (cm^2/h), total potential exposure	TC (cm^2/h) assuming arm, body and legs covered (bare hands)	TC (cm^2/h), covered body and gloves	Applicable to the following crops	EUROPOEM II details	Actual EUROPOEM value used in exposure calculator	US EPA—TC	Task details
Strawberries	Reach/pick	Hand and forearm	3 000	3 000	750	Berries and other small fruit, low	Arithmetic means = 2 500 cm^2/h hands, hands and forearms = 3 670 cm^2/h —adjusted to 3 000 cm^2/h as value wash high (inexperienced pickers) with gloves assuming 10-fold reduction = 750 cm^2/h (own calculation)	3 000	1 100	Hand harvesting
Ornamentals	Cut/sort/bundle/carr y	Hand and body	14 000	5 000	1 400	Ornamentals and nursery	75^{th} = 4 000 cm^2/h hands 90^{th} = 10 000 cm^2/h body hands and body = 14 000 cm^2/h 10-fold reduction for protective clothing total = 5 400 cm^2/h approx. 5 000 with gloves same method = 1 400 cm^2/h (own calculation)	5 000	4 800 (floriculture) 230 (ornamentals)	Hand harvesting
Golf course, turf or other sports lawns	Maintenance	Hand and body	5 800	2 500	580				3 700	Maintenance
General	Inspection, irrigation	Hand and body	12 500, 7 500 (lower legs and arms uncovered)	1 400	No justified proposal possible	Cereals Grassland and lawns Hops Oilseeds Root and tuber vegetables Sugar plants			1 100 6 700 640 1 100 210 8 800	Scouting Maintenance Scouting Scouting Scouting Hand harvesting (sugar cane)

TC, transfer coefficient.

GLOSSARY

Acceptable Operator Exposure Level (AOEL): The reference value against which non-dietary exposures to pesticides are currently assessed. It is intended to define a level of daily exposure throughout a spraying season, year on year, below which no adverse systemic health effects would be expected. The AOEL is normally derived by applying an assessment factor (most often 100) to a No Observed Adverse Effect Level (NOAEL) (corrected if appropriate for incomplete absorption) from a toxicological study in which animals were dosed daily for 90 days or longer. Less often, the critical NOAEL comes from a study with a shorter dosing period (e.g. a developmental study).

Actual dermal exposure: Exposure to the skin that would occur in the presence of clothing and/or personal protective equipment.

Acute Acceptable Operator Exposure Level (AAOEL): A term used to describe a reference value against which acute non-dietary exposures (i.e. those that might be incurred in a single day) could be assessed. This would be relevant only to those plant protection products for which such exposures might produce significant toxicity.

***Ad hoc* exposure assessment**: An assessment of exposures incorporating data specific to one or more uses of a particular plant protection product, which is considered to provide a more reliable estimate of potential exposure than the normal first tier approach using more generic data.

Aggregate risk assessment: Risk assessment that takes into account all pathways and routes of exposure to a single chemical.

Bystanders: Persons who could be located directly adjacent to the area where PPP application or treatment is in process or has recently been completed; whose presence is quite incidental and unrelated to work involving PPPs, but whose position might lead them to be exposed; and who take no action to avoid or control exposure.

Cumulative risk assessment: Risk assessment for combined exposure to two or more chemicals by all relevant pathways and routes.

Dislodgeable foliar residue (DFR): The residue of a pesticide following deposition on foliage or fruit, which can be transferred to a person through contact with the foliage or fruit.

Drift (expressed as percentage of areic mass): The deposition of a substance per unit receiving (non-target) surface, expressed as a percentage of the amount applied per unit area target surface. For example, at 1 % drift, the deposition per square metre is 1 mg when the dosage is 1 kg per ha (100 mg per square metre).

Engineering controls: Methods of reducing exposure to pesticides (or other hazardous agents) through appropriately designed equipment (e.g. a closed tractor cab with air filtration).

Filtration unit (on a tractor cab): A device that removes pesticide residues from the air that enters a closed tractor cab.

Formulation: The composition of a pesticide product as supplied.

Good Agricultural Practices: “Practices that address environmental, economic and social sustainability for on-farm processes, and result in safe and quality food and non-food agricultural products”; see http://www.fao.org/docrep/meeting/006/y8704e.htm

Hand to mouth transfer: Transfer of pesticide residues from contaminated surfaces to the mouth via the hand: potentially a significant pathway of exposure, especially in infants and toddlers.

In-use preparation: The form in which a pesticide is applied after any dissolution, dilution or mixing of the product as supplied.

Least squares regression: Ordinary least squares regression is the common method for fitting linear regression models to data. Once fitted, the expected value (mean) can be predicted, as can any required percentile (by adding the respective variation to the predicted value). However, the method assumes normality of the distribution at each exposure level and uniform variation over the whole range. Least squares regression is also sensitive to outliers and in particular to the assumed values of measurements below the limit of quantification. These assumptions may be violated by peculiarities of a given dataset, especially by the presence of non-detected values (see quantile regression).

Log-normality: The nature of a statistical distribution in which the logarithms of individual measurements have a Gaussian or "normal" distribution. For a given scenario, measurements of individual exposures often have a log-normal distribution.

Non-professional operators: People who apply plant protection products non-occupationally; for example, in their gardens.

Normalisation (of exposure): Adjustment of exposure estimates to take account of the amount of a product handled or applied.

Object to mouth transfer: Transfer of pesticide residues to the mouth from contaminated objects through placement of the object in the mouth—a pathway of exposure of greatest importance in infants and toddlers.

Operators: Persons who are involved in activities relating to the application of a plant protection product; such activities include mixing/loading the product into the application machinery, operation of the application machinery, repair of the application machinery whilst it contains the plant protection product, and emptying/cleaning the machinery/containers after use. Operators may be either professionals (e.g. farmers or contract applicators engaged in commercial crop production) or amateur users (e.g. home garden users).

Parametric: Relating to a summary characteristic of the (theoretically infinite) population from which a sample is derived. Population parameters can be estimated from corresponding sample statistics. For example, a sample mean may provide an estimate of the mean of the population from which the sample was derived.

Para-occupational exposure: Exposure of other members of a professional operator's household that occurs as a consequence of transfer of residues from his clothing or person in the home.

Percentile: A value that partitions a distribution of measurements at a specific point when they are ranked in ascending order of magnitude. For example, the 75th percentile from a sample of measurements is a value that is ≥ 75 % of the measurements and ≤ 25 % of the measurements.

Personal protective equipment (PPE): Certified equipment worn by an operator or worker that is designed to reduce hazardous exposures (e.g. gloves, coveralls, face masks).

Potential dermal exposure: Exposure to the skin that would occur in the absence of clothing or personal protective equipment.

Product: A pesticide preparation as supplied. It includes not only the active substance(s), but also co-formulants such as emulsifiers, solvents and safeners.

Quantile regression: A non-parametric method which gives an independent estimate for every percentile providing a view of possible relationships between variables (Koenker, 2005). As long as the percentile is well within the range of measured data, the resulting fit can be expected to be more robust than the least squares fit. In particular, it will not depend on the actual choice of the value substituted for non-detects and does not assume the variability to be independent of the quantity of predictor variable(s) (see least squares regression).

Re-entry: Activities performed in the field after the application:

- reach/pick
- search/reach/pick
- harvesting and other activities (e.g. leaf pulling and tying)
- cut/sort/bundle/carry
- maintenance
- inspection, irrigation.

Residents: Persons who live, work or attend school or any other institution adjacent to an area that is or has been treated with a plant protection product; persons whose presence is quite incidental and unrelated to work involving plant protection products but whose position might lead them to be exposed; persons who take no action to avoid or control exposure; or persons who might be in the location for 24 hours per day.

Saliva extraction percentage: The fraction (expressed as a percentage) of pesticide extracted from a contaminated hand or object via saliva.

Systemic exposure: Exposure of organs and tissues that occurs following absorption and distribution of a chemical in the body.

Task-specific factor (worker re-entry): A factor (with units ha/h × 10^{-3}) relating to a specified task carried out by a re-entry worker (e.g. cutting ornamentals). It is multiplied by the rate at which a pesticide was applied to derive an estimate of potential exposures through inhalation.

Transfer coefficient: The rate at which dislodgeable foliar residues can be transferred to a worker during a specified activity (expressed in terms of the area of contaminated foliage or fruit from which residues are transferred per hour).

Turf transferable residue: Equivalent to a dislodgeable foliar residue for residues of plant protection products deposited on lawns.

Workwear (operator): Normal workwear will consist of coveralls or long-sleeved jackets and trousers that were made of cotton (> 300 g/m^2) or cotton/polyester (> 200 g/m^2).

Workers: In the context of this opinion, the term worker refers to persons who, as part of their employment, enter an area that has been treated previously with a plant protection product, or who handle a crop that has been treated with a plant protection product.