GUIDANCE OF EFSA

Guidance on the Assessment of Exposure for 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 has the purpose to ensure that the residues of the plant protection products, 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, Bystanders and Residents (EFSA Journal 2010;8(2):1501), which highlighted some inconsistencies between the approaches adopted by regulatory authorities. Therefore, the PPR Panel proposed a number of changes to practice in use (e.g. routine risk assessment for individual PPPs should continue to use deterministic methods, and that a tiered approach to exposure assessment remains appropriate; need of introducing 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 centiles of relevant data sets, whereas for longer term risk assessments, the starting point should be a 75th centile). To prepare a Guidance Document an *ad hoc* working group was established to revise all the available data and procedures to perform the operator, worker, bystander and resident risk assessment. In addition to what 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. A calculator reflecting the content of the guidance is annexed to it, to support stakeholders in performing the assessment of exposure and risk.

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KEY WORDS

exposure, operator, worker, bystander, resident, estimation, guidance, calculator

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SUMMARY

(To be inserted)

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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, Bystanders and Residents”. 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, Bystanders and Residents.

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, bystanders and residents.
- 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 operator 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 that was presented as part of a published opinion of the EFSA PPR Panel (EFSA, 2010) and readers are referred to that opinion for an explanation of the rationale underlying the methods that it describes.

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

A 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 potential systemic exposure that can be compared with appropriate toxicological reference values.

Risk assessments must be carried out for all scenarios of exposure to 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 only be done where there is good ground for concluding that the *ad hoc* method will provide a more reliable and realistic exposures arising from the proposed Good Agricultural Practice for potential exposure than the standard method. This conclusion must take into account the quality and quantity of data underpinning the *ad hoc* assessment as 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, bystanders and residents. For the evaluation of active substances and plant protection products 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, and no well-standardised methods are available to assess the exposures of bystanders and residents, and different Member States follow different approaches.

The activity of the working group started from the assessment of the available databases to be considered for the preparation of the Guidance.

A basic principle of the present Guidance and the annexed calculator (see Appendix F) are the transparency of data, the traceability of information and the reproducibility of the outcomes. Therefore, it was decided that only databases for which the working group had access to the raw data and that could be circulated, if requested by third parties, according to the Aarhus convention were considered. 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 to address some of the shortcomings that have been highlighted in current methodology. The Guidance can subsequently be reviewed and, if appropriate, 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 in 2014). 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 exposure.

Table 1: Overview of database availability

Exposed category	Database/model	Availability of raw data		Reference
		Yes	No	
Operator (field)	German model	x		Lundehn J.-R., Westphal D., Kieczka H., Krebs B., Löcher-Boltz S., Maasfeld W., Pick E.D. (1992). Uniform principles for safeguarding the health of applicators of plant protection products. Mitteilungen aus der Biologischen Bundesanstalt für Land und Forstwirtschaft, Heft 277, Berlin, Germany
Operator (field)	UK POEM	x		Scientific Subcommittee on Pesticides and British Agrochemicals Joint Medical Panel., Estimation of Exposure and Absorption of Pesticides by Spray Operators (UK MAFF) 1986 and the Predictive Operator Exposure Model (POEM - UK MAFF) 1992

[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. Official Journal L 230, 1-290. 19 August 1991

[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. Official Journal L 309, 1-50. 24 November 2009.

Exposed category	Database/model	Availability of raw data		Reference
		Yes	No	
Operator (field)	Agricultural operator exposure model (AOEM)	x		Joint development of a new Agricultural Operator Exposure Model - Project Report, 2013-01-29, Federal Institute for Risk Assessment (BfR) [1], Health and Safety Executive (HSE) [2], French Agency for Food, Environmental and Occupational Health and Safety (ANSES) [3], Federal Research Centre for Cultivated Plants (JKI) [4], Federal Office of Consumer Protection and Food Safety (BVL) [5], German Crop Protection Pest Control and Fertilizer Association (IVA) [6], European Crop Protection Association (ECPA) [7] ,observed by EFSA [8] and TNO [9], [1] Großkopf, C., Martin, S., Mielke, H., Westphal, D., [2] Hamey, P., [3] Bouneb, F., [4] Rautmann, D., [5] Erdtmann-Vourliotis, M., [6] IVA Expert Committee for Operator Safety, [7] ECPA Occupational and Bystander Exposure Expert Group, [8] Tiramani, M., [9] Gerritsen, R., Spaan, S. http://www.bfr.bund.de/cm/350/joint-development-of-a-new-agricultural-operator-exposure-model.pdf and http://www.springerlink.com/openurl.asp?genre=article&id=doi:10.1007/s00003-013-0836-x
Operator (field)	EUROPOEM II	x		EUROPOEM II. (2002) The Development, Maintenance and Dissemination of Generic European Databases and Predictive Exposure Models to Plant Protection Products, FAIR3 CT96-1406, Final report.
Operator (field)	PHED	x		PHED, (1992). US Environmental Protection Agency, Health and Welfare Canada, National Agricultural Chemicals Association. Vesar Inc., Springfield, USA.
Operator (field)	TNsG Biocides		x	TNsG. (2008) Human exposure to biocidal products - Technical Notes for Guidance Available at: http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/TNsG/TNsG_ANNEX_I_INCLUSION/TNsG-Annex-I-Inclusion.pdf http://echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf
Amateur	ConsExpo		x	ConsExpo 4.0 Consumer Exposure and Uptake Models http://www.rivm.nl/en/Library/Scientific/Models/Download_page_for_ConsExpo_software

Exposed category	Database/model	Availability of raw data		Reference
		Yes	No	
Amateur	French data		x	Unpublished UPJ, Union des Entreprises pour La Protection des Jardins (UPJ) - CEHTRA Consultancy for Environmental & Human Toxicology and Risk Assessment (CEHTRA)
Operator (greenhouse)	Industrieverband Agrar (IVA) - Germany	x		Mich, G., 1996. Operator Exposure in greenhouse during practical use of plant protection product. ECON Forschungs- und Bewertungskonzepte für Umwelt und Gesundheitssicherheit GmbH. Ingelheim. Unpublished.
Operator (greenhouse)	Southern Europe		x	Unpublished ECPA model
Operator (greenhouse)	Dutch		x	Unpublished 1992, Dutch authorities, (data open literature)
Operator (seed treatment)	SeedTropex		x	Unpublished 1996, UK – FR, Industry data
Worker	EUROPOEM II	x		EUROPOEM II. (2002) Post-application Exposure of Workers to Pesticides in Agriculture - Report of the Re-entry Working Group, J.J. van Hemmen, G. Chester, P. Hamey, J. Kangas, E. Kirknel, W. Maasfeld, J. Perkins, J. Phillips, C. Schulze-Rosario, FAIR3-CT96-1406.
Worker	German	x		Lundehn J.-R., Westphal D., Kieczka H., Krebs B., Löcher-Boltz S., Maasfeld W., Pick E.D. (1992). Uniform principles for safeguarding the health of applicators of plant protection products. Mitteilungen aus der Biologischen Bundesanstalt für Land und Forstwirtschaft, Heft 277, Berlin, Germany
Worker (fork lift driver, sowing)	SeedTropex		x	Unpublished 1996, UK – FR, Industry data
Worker	Transfer coefficient		x	US EPA (U. S. Environmental Protection Agency), 2000. Agricultural Transfer Coefficients. Policy No. 003.1 (dated August 7). Science Advisory Council for Exposure, Health Effects Division, Office of Pesticide Programs, Washington, D.C.
Residents and bystanders	EUROPOEM II	x		EUROPOEM II. (2002) Post-application Exposure of Workers to Pesticides in Agriculture - Report of the Re-entry Working Group, J.J. van Hemmen, G. Chester, P.Hamey, J. Kangas, E. Kirknel, W. Maasfeld, J. Perkins, J. Phillips, C. Schulze-Rosario, FAIR3-CT96-1406.
Residents and bystanders	BREAM (Bystander and	x[1]		Silsoe Spray Application Unit, The Arable Group;

Exposed category	Database/model	Availability of raw data		Reference
		Yes	No	
	Resident Exposure Assessment Model)			http://randd.defra.gov.uk/Document.aspx?Document=11392_PS2005Finalreportforpublication.pdf Bystander exposure to pesticide spray drift: New data for model development and validation Biosystems Engineering, Volume 107, Issue 3, November 2010, Pages 162-168 M.C. Butler Ellis, A.G. Lane, C.M. O'Sullivan, P.C.H. Miller, C.R. Glass The Silsoe Spray Drift Model: A model of spray drift for the assessment of non-target exposures to pesticides Biosystems Engineering, Volume 107, Issue 3, November 2010, Pages 169-177 M.C. Butler Ellis, P.C.H. Miller Modelling the dispersion of volatilised pesticides in air after application for the assessment of resident and bystander exposure Biosystems Engineering, Volume 107, Issue 2, October 2010, Pages 149-154 M.C. Butler Ellis, B. Underwood, M.J. Peirce, C.T. Walker, P.C.H. Miller Glass, C. R., Mathers, J. J., Harrington, P., Miller, P. C. H., Butler Ellis, C., Lane, A., et al. (2010). Generation of field data for bystander exposure and spray drift with arable sprayers. Aspects of Applied Biology, 99, 271-276, International Advances in Pesticide Application. Development of techniques to measures vapour concentrations of pesticides to determine potential bystander & resident exposure C R GLASS, J J MATHERS, M T HETMANSKI, M SEHNALOVA & R J FUSSELL (2012) Aspects of Applied Biology, 114, 79-86, International Advances in Pesticide Application. Probabilistic risk assessment of bystander and resident exposure to spray drift from an agricultural boom sprayer M C KENNEDY, M C BUTLER ELLIS & P C H MILLER, (2012), Aspects of Applied Biology, 114, 87-90, International Advances in Pesticide Application.
Residents and bystanders	ConsExpo		x	ConsExpo 4.0 Consumer Exposure and Uptake Models http://www.rivm.nl/en/Library/Scientific/Mod

Exposed category	Database/model	Availability of raw data		Reference
		Yes	No	
				els/Download_page_for_ConsExpo_software
Residents and bystanders	Lloyd and Bell 1983 and 1987 (spray drift values)	x		Lloyd & Bell, 1983. Hydraulic nozzles: comparative spray drift study (MAFF/ADAS). Lloyd et al, (1987). Orchard sprayers: comparative operator exposure and spray drift study (MAFF/ADAS)
Residents and bystanders	CRD 2008	x		Available at: http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/enforcement/resident-and-bystander-exposure-to-pesticides
Residents and bystanders	California EPA	x		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		Ganzelmeier/Rautmann, 1995. Studies on the spray drift of plant protection products. Mitteilungen aus der BBA für Land- und Forstwirtschaft Berlin-Dahlem, Heft 305, 113 Rautmann, D., Streloke, M. and R. Winkler. 2001. New basic drift values in the authorization procedure for plant protection products. Mitt. Biol. Bundesanst. Land-Forstwirtsch. No. 383. Berlin

[1]public data only

3. Definitions of exposed groups

For the purpose of this Guidance, the following definitions have been adopted (EFSA, 2010):

- **Operators** are: persons who are involved in activities relating to the application of a plant protection product (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 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).

- **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 24 hours per day (longer term exposure).

Operators, workers, bystanders and residents 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, exposure pathways other than dermal or inhalation in most cases are not considered to contribute significantly to the overall body burden of the pesticide, except for the hand or object to mouth transfer for toddlers. It should also be taken into account that the exposure estimated with the Guidance in principle considers conservative approaches, and is assumed to also cover minor exposure pathways.

4. Overall approach

Step one: 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 one day. The answer to this second question will be determined as part of the toxicological evaluation (it will normally be relevant also 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 below.

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

	Risk assessments that may be required	
Exposed group	**PPPs with no potential for systemic toxicity from exposure during one day (no AAOEL)**	**PPPs with potential for systemic toxicity from exposure during one day (AAOEL)**
Operators	**L**	**A, L**
Workers	**L**	**A, L**
Residents	**L**	**A, L**
Bystanders	**L** *)	**A**

A = acute risk assessment, L = longer term risk assessment
*) worst case to cover exposure incidents during one day

Acute exposure assessments are required for both residents and bystanders; for residents longer-term exposure assessments are also required.

The exposure assessments have to be compared to the specific reference values, i.e. the AOEL and the AAOEL. In the calculator attached to this Guidance (see appendix F), a cell for data entry of the AAOEL is available: however, as no methodology is currently available for its setting, an acute risk assessment cannot be performed (in the calculator a warning will appear).

Step two: Use standardised first tier methods of exposure assessment where available

For each risk assessment that is deemed necessary, potential daily exposures should if possible be assessed using standardised methods. 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 – e.g. 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 – e.g. 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, for example during mixing and loading, spraying or in some cases when acting as a worker in the same day. However, in 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 only representing the worst case.

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 12.

<u>Step three: 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.</u>

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 can be applied. This will normally be based on higher tier field study with the necessary number of replicates.
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 centile of the distribution of measurements in the sample; and b) a statistical estimate of the 95th centile for the theoretical population of measurements from which the sample was derived, under the assumption that this population has a log-normal distribution (EFSA, 2010).

For risk assessments in relation to longer term exposures, exposures should as a default be derived as the higher of: a) the 75th centile of the distribution of measurements in the sample; and b) a statistical estimate of the 75th centile for the theoretical population of measurements from which the sample was derived, under the assumption that this population has a log-normal distribution (EFSA, 2010).

Statistical estimates of centiles 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 centile.

The reason for including the statistical estimates of population parameters is that sample centiles may by chance be unrepresentatively low, especially when the sample is relatively small and it is a high centile 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 only a small sample of relevant exposure measurements is available, a decision must be made as to whether 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 centile estimates (e.g. by using upper confidence limits for parametrically estimated centiles, or a higher than normal centile from the sample of measurements).

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

<u>Step four: Higher tier exposure assessment</u>

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 where 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, 2010), unless otherwise specified.

5.1. Body weights

In all calculations, it should be assumed as a default that adults have a body weight of 60 kg, and that default body weight for children aged less than 3 years is 10 kg.

- Adult body weight 60 kg
- Child body weight (< 3 years old) 10 kg

According to the EFSA GD on default values[6] a body weight of 70 kg should be used as default for the European adult population (above 18 years old). The Scientific Committee considers that using 70 rather than 60 kg is a more realistic estimate of the average bodyweight of the European adult population for consumer risk assessment. 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. Therefore, for this Guidance Document 60 kg is proposed to cover also teenagers and young adults, or females working in horticulture. These values are also in line with what recent HEEG Opinion[7].

The selection of 10 kg bw for children is assumed to represent a worst case for the scenarios considered for children up to 11 years-old exposed as bystanders and residents. Children less than one year-old, which would be represented by a lower body weight, are normally not expected to be exposed through entry into treated fields, 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:

Table 3: Daily inhalation rates (for longer term exposures) (modified from EFSA, 2010)

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

[6] 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

[7] 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

Similar to body weights, the inhalation rate of children 1 to less than 3 years old was selected to also be protective for other age groups. The inhalation rate of children less than 1 year old is higher, however if considered together with the dermal exposure of the relevant exposure of children 1 to less than 3 years 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 follows:

Table 4: Hourly inhalation rates (for acute exposures) (modified from EFSA, 2010)

Age Group	**High Intensity Hourly Inhalation Rate, adjusted for body weight (m^3/hour/kg)**
<1 year	1 to 3 years: 0.19 (worst case across the available scenarios up to 11 years old children)
1 to 3 years	
11 to <16 years	Adults (including adolescents ≥11 years old): 0.04
Adults	

As for operators and workers exposure values might need to be recalculated 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:

- non volatile and semivolatile substances 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)
- 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

In Table 5 the default numbers of treated hectares per day according to the type of crops and the application technique are given. The number of ha treated reflect the technical standard of the equipment used in the original studies underpinning the exposure data. In practice the treated area will depend on the type of equipment used. Greater areas may be treated using more sophisticated equipment. With relatively simple equipment (often used in studies at the basis of older models), the areas treated per day are not expected to exceed those proposed. 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

	Area treated per day (ha)	
Crops	**Hand-held equipment [1)]**	**Vehicle mounted equipment [2)]**
Bare soil [3)]	**4 / 1**	**50 / 20**
Berries and other small fruits (low) [4)]	**4 / 1**	**50 / 20**
Brassica vegetables	**4 / 1**	**50 / 20**

	Area treated per day (ha)	
Crops	**Hand-held equipment [1)]**	**Vehicle mounted equipment [2)]**
Bulb vegetables	**4 / 1**	**50 / 20**
Cane fruit	**4 / 1**	**10 / 8**
Cereals	**4 / 1**	**50 / 20**
Citrus fruit	**4 / 1**	**10 / 8**
Fruiting vegetables	**4 / 1**	**50 / 20**
Golf course turf or other sports lawns [4)]	**4 / 1**	**50 / 20**
Grassland and lawns	**4 / 1**	**50 / 20**
Grapes	**4 / 1**	**10 / 8**
Hops	**4 / 1**	**10 / 8**
Leaf vegetables and fresh herbs	**4 / 1**	**50 / 20**
Legume vegetables	**4 / 1**	**10 / 8**
Oilfruits	**4 / 1**	**10 / 8**
Oilseeds	**4 / 1**	**50 / 20**
Ornamentals	**4 / 1**	**10 / 8**
Pome fruit	**4 / 1**	**10 / 8**
Root and tuber vegetables	**4 / 1**	**50 / 20**
Stone fruit	**4 / 1**	**10 / 8**
Tree nuts	**4 / 1**	**10 / 8**

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

2) The first value should be used for more sophisticated application equipment (according AOEM), the second value should be used for other models.

3) In the calculator (see appendix F) there are no specific data on bare soil; however it was considered that the same data as for application in low crops, tractor mounted, can be used, with the exception that no re-entry exposure is foreseen.

4) 20 ha treated per day is considered quite conservative by the WoG.

In the 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);
- Bystander: 0.25 hours (default for crop entry activity);
- Resident: 2 hours (default for resident on lawn; dermal, surface deposits), 0.25 hours (dermal, entry into treated crops) and 24 hours (inhalation from vapour).

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 calculator; if above 80%, the calculator will automatically consider 100% oral absorption
- Dermal: to be determined according to Guidance on Dermal Absorption - EFSA Panel on Plant Protection Products and their Residues. EFSA Journal 2012;10(4):2665. For the dermal absorption percentage to be used for the assessment of worker, bystander and resident exposure towards surface deposits, the higher of the values for the undiluted product and the in-use dilution should be used.

5.7. Default surface area of body parts

Table 6: Default values for surface area of the various parts of the body (from the **HEEG OPINION “**Default human factor values for use in exposure assessments for biocidal products)

DEFAULT VALUES FOR BODY WEIGHT AND BODY PART SURFACE AREAS FOR THE INFANT, TODDLER, CHILD AND ADULT				
	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 cm2	230.4 cm2	427.8 cm2	820 cm2
Arms (both)	Upper = 352.6 cm2 Lower = 229.6 cm2 Total = 582.2 cm2	Upper = 412.8 cm2 Lower = 268.8 cm2 Total = 618.6 cm2	Upper = 772.8 cm2 Lower = 496.8 cm2 Total = 1269.6 cm2	Upper = 1141.2 cm2 Lower = 1128.8 cm2 Total = 2270 cm2
Head	344.4 cm2	403.2 cm2	529 cm2	1110 cm2
Trunk (bosom, neck, shoulders, abdomen, back, genitals and buttocks)	1533.4 cm2	1795.2 cm2	3376.4 cm2	5710 cm2
Legs (both legs and thighs)	1041.4 cm2	1219.2 cm2	2741.6 cm2	5330 cm2
Feet (both)	246 cm2	288 cm2	604.9 cm2	1130 cm2
Total body surface area	4100 cm2	4800 cm2	9200 cm2	16600 cm2
Table 7-12 in US EPA/ Exposure Factors Handbook, Nov 2011 (data based on US EPS 1985, and NHANES 2005-2006) informs that the 25th percentile surface area for adult male forearms is 1320 cm2 which equates to 6.8 % of the 25th percentile for the total body surface area for the male (19300 cm2). 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. Thus for the adult female, the surface area of both forearms is calculated to be 16600 x 6.8/100 = 1128.8 cm2 .				

6. Methods for first tier exposure assessment

6.1. Operator exposure

Exposure is estimated for the recommended conditions of use of the plant protection product. This is normally done separately for the mixing/loading and the application tasks. 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%). The exposures for individual tasks are the sums of the dermal exposures and the inhalation exposures. Where an operator can be 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 Acceptable Operator Exposure Level (AOEL) or the Acute Acceptable Operator Exposure Level

(AAOEL) as appropriate[8]. However, as no methodology is currently available to define an AAOEL, an acute risk assessment cannot be performed (in the calculator a warning will appear).

Currently, models established over 20 years ago (e.g. UK POEM, German model) are the standards to assess exposure of agricultural operators to plant protection products, but they do not reflect current application techniques. A new predictive model for the estimation of agricultural operator exposure has been developed (AOEM 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 and is applicable for national or zonal authorisation of plant protection products as well as for approval of active substances in plant protection products. Thirty-four unpublished exposure studies conducted between 1994 and 2009 were evaluated for the new model. To ensure a very high quality of data the studies had to meet a set of quality criteria, e.g. GLP conformity and compliance with OECD guidance. Exposure data and supplementary information on the trials 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 for indoor scenario, however activities during mixing/loading for outdoor and for indoor application should be comparable. As a major factor contributing to the exposure of operators, the amount of active substance used per day was identified. Other parameters such as formulation type, droplet size, and presence of a cabin or density of the canopy were selected as factors for sub-scenarios. For two scenarios the corresponding datasets were too small to identify reliable exposure factors; instead the relevant percentiles of the exposure distribution were used. In 2013, the new model became available and has been reviewed by MS. The whole project report on the development of the new model (including the underlying study data) is published.

The AOEM model was considered by the WoG as suitable for inclusion in the EFSA Guidance Document and its calculator, as it is reflecting 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, not comparable to the old 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 percentiles was developed for future uses). 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 Table 7 and Table 8).

Mixing/loading values from AOEM can also be considered as representative for weed wiper equipment as long as no further data are available.

[8] It is noted that an EFSA activity is ongoing with regard to setting reference values including AOEL and AAOEL. Possible developments could impact on the presented assessments.

Table 7: 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)

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
	total 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
	total 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
	total 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
	total 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
	total 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
	total 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 8: 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)

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
	total 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
	total 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
	total 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
	total 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
	total 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
	total 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, 2010) covering partly additional scenarios (e.g. granular application or indoor 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 9, 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 exposure/kg a.s. handled (Table 9, 10 or 11 as appropriate), the area treated (ha/day) (Table 5), and the recommended amount of active substance applied (kg a.s./ha).

Where specific exposures do not assume the use of PPE, the unprotected individual is assumed to wear shorts and a T-shirt. Where the risk assessor is confident that normal work wear will comprise coveralls or long-sleeved jackets and trousers this can be used as alternative assumption. Where PPE will be used, exposures can be modified to reflect this, by multiplying the appropriate values in Tables 9, 10 and 11 by the protection (i.e. per cent penetration/transfer) factors shown in Table 12.

Table 9: Additional models for specific exposures during mixing/loading (potential exposures except where indicated otherwise) (adapted from EFSA, 2010)

Application equipment	Formulation type	Type of exposure	mg exposure/kg a.s. mixed/loaded		Model	Comments
			75th Centile	95th Centile		
1. Vehicle-mounted	ii. GR, FG	Hands	0.0015	0.0069	PHED	NB: Scenario "without RPE/PPE" includes wearing protective gloves
		Body	0.0162	0.0427	PHED	NB: Scenario "without RPE/PPE" includes wearing protective coverall
		Inhalation	0.0208	0.0784	PHED	

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 10: Additional models for specific exposures during application

	Application method	Application equipment	Type of exposure	mg exposure/kg a.s. applied		Model	Comments
				75th percentile	95th percentile		
Outdoor/ Indoor	Broadcast application of granules	Vehicle-mounted	Hands	0.0004	0.0013	PHED	NB: Scenario "without RPE/PPE" includes wearing protective gloves
			Body	0.0047	0.0151	PHED	NB: Scenario "without RPE/PPE" includes wearing protective coverall
			Inhalation	0.0012	0.0045	PHED	
	In furrow application of granules	Vehicle-mounted	Hands	0.0004	0.0013	PHED	NB: Scenario "without RPE/PPE" includes wearing protective gloves
			Body	0.0047	0.0151	PHED	NB: Scenario "without RPE/PPE" includes wearing protective coverall

Outdoor/ Indoor	Application method	Application equipment	Type of exposure	mg exposure/kg a.s. applied		Model	Comments
			Inhalation	0.0012	0.0045	PHED	
	Manual application of granules	Manual	Hands	28.5320	94.3636	PHED	NB: Scenario "without RPE/PPE" includes wearing protective gloves; value is for combination of mixing&loading and application
			Body	68.8708	253.4433	PHED	NB: Scenario "without RPE/PPE" includes wearing protective coverall; value is for combination of mixing&loading and application
			Inhalation	0.4677	1.5251	PHED	NB: Value is for combination of mixing&loading and application
	Weed wipers	Vehicle-mounted	Hands	0.8455	10.6195	EUROPOEM	
			Body	0.9169	4.7069	EUROPOEM	
			Inhalation	0.0112	0.0781	EUROPOEM	

The possibility of using water soluble bags was considered: available data indicate that exposure to PPPs during mixing and loading is limited but not negligible. Based on expert judgement and approaches at national level, the WoG decided that the exposure deriving from ML activities of water soluble bag should be 10% of the corresponding formulation (only for solid formulation, powders and granules, as for liquids there are very few data).

Use of Personal Protective Equipment

According to 'Good agricultural practice' and considering occupational hygiene measures, first tier exposure assessments for operators should be performed using work clothing. (a description is given in the glossary).

In exposure assessments, the following levels of protection 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 5% can be considered for re-entry activities:
- Coveralls (whole body) or a single layer of work clothing (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 25-10%, and dermal exposure (head) to 80%.

Further refinements with different protection factors could be considered at MSs level based on national conditions. The proposed protection factors are given in Table 12:

Table 11: Default personal protective equipment (PPE) (modified from EFSA, 2010)

Technical control/PPE item		Protection 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 5% (	Dermal exposure – hands only
Working clothing or uncertified cotton coverall		Operators 10%	Dermal exposure – body only
Protective coverall **(*this is used <u>instead of</u> working clothing/uncertified cotton coverall)***		Operators certified protective coverall 5%	Dermal exposure – body only
Hood and visor*		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%	Inhalation exposure
		80%	Dermal exposure – head only
	FFP2, P2 and similar	10%	Inhalation exposure
		80%	Dermal exposure – head only

°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.
*Hood and visor are considered in alternative to the RPE

In the AOEM model 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 cannot be applied.
For other models a certified coverall provides a 5% protection factor; consideration of the effect of wearing garment providing greater protection has to be considered outside of the calculator and in discussion with MS authorities as there is not a harmonised classification of protection factors.

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 the data. For the calculator the longer term exposure was mainly considered. It is noted that the database contains some weaknesses due to the limited dataset and the statistical uncertainties.

Exposure should be estimated for activities that could entail contact with treated crops, either through re-entry of a treated area after application (e.g. for crop inspection/harvesting activities) or through other activities such as sorting and bundling. Currently, the only data we have allow calculations for re-entry immediately after the application solution has dried. No further data is available. Any further refinement in case data is 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 protected crops grown in glasshouses.

Some scenarios involving exposure to PPPs (or their relevant metabolites, degradation and reaction products) through dislodgeable foliar residues (DFR) may also entail exposure to soil-borne residues (e.g. harvesting leeks or weeding in a leafy crop). In these situations, estimates of dermal exposure should include any exposure through soil contact as well as that arising from contact with foliage.

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 G 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 shorts and a T-shirt. Where the risk assessor is confident that normal work wear will comprise coveralls or long-sleeved jackets and trousers, this can be used as alternative assumption. If it is considered that workers can be reliably expected to use personal protective equipment, then allowance for this can be made in exposure estimation by application of respective transfer coefficients (TC) as specified in Table 14.

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 [$\mu g/cm^2$] x TC [cm^2/h] x T [h/day])/1000

The default value for time of exposure should be taken as 8 hours for harvesting and maintenance type activities and 2 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) (the reference document is the 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 dislodgeable foliar residue 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 (EUROPOEM 2002: The 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 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 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 is available and where 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 Annexes D and E to this Guidance) indicating possible DT50 values up to and exceeding 30 days for some a.s.), the dissipation should be taken into account by application of an appropriate multiple application factor (MAF), examples of which are given in Table 13.

The default value of 30 days should only be used when no data is reported for DT50 or half-life in Annexes D and E of this guidance. For new a.s. it will be possible to include in the calculator new experimental data 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, 2010)

	Number of applications											
Interval between applications (days)	**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

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 14 are based and modified from EUROPOEM (EUROPOEM II, 2002 under consideration of EPA values). These values should be used in first tier assessments of potential dermal exposure for the seven 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 ten-fold by clothing covering the arms, body and legs. In situations where T-shirts and/or shorts are worn, exposures may be higher than these estimates, and potential exposure should be estimated using the values in the fourth column of the Table 14.
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 (modified from EUROPOEM, 2002, considering EPA, 2012)

Crop	Nature of task	Main body parts in contact with foliage	Transfer Coefficient (cm^2/h) total potential exposure	Transfer Coefficient (cm^2/h) assuming arm, body and legs covered (bare hands)	Transfer Coefficient (cm^2/h) Covered body and gloves	Applicable to the following crops
Vegetables	Reach / Pick	Hand and body	5800	2500	580	• Brassica vegetables • Fruiting vegetables • Leaf vegetables and fresh herbs • Legume vegetables • Bulb vegetables
Tree fruits	Search / Reach / Pick	Hand and body	22500	4500	2125	• Citrus • Cane fruits • Oilfruits, • Pome fruits • Stone fruits • Tree nuts
Grapes[1]	Harvesting and other activities (e.g. leaf pulling and tying)	Hand and body	30000	10100	no justified proposal possible	
Strawberries	Reach / Pick	Hand and forearm	3000	3000	750	• Berries and other small fruit, low
Ornamentals	Cut / Sort / Bundle / Carry	Hand and body	14000	5000	1800	• Ornamentals and Nursery
Golf course, turf or other sports lawns	Maintenance	Hand and body	5800	2500	580	
General	Inspection, irrigation	Hand and body	3600	1100	no justified proposal	• Cereals • Grassland

Crop	Nature of task	Main body parts in contact with foliage	Transfer Coefficient (cm²/h) total potential exposure	Transfer Coefficient (cm²/h) assuming arm, body and legs covered (bare hands)	Transfer Coefficient (cm²/h) Covered body and gloves	Applicable to the following crops
					possible	and lawns • Hops • Oilseeds • Root and tuber vegetables • Sugar plants

[1] EPA data were used even if the underline data are not available as it is clear that grapes harvesting might be a scenario of concern for which EU data are missing. As for inspection activities, the EPA values are considered to be appropriate, in absence of the supporting data, when compared to the exposure values for other tasks. [2]US EPA TC value

In the Appendix H a comparison of the TC values proposed in this Guidance and the values used in the USEPA is reported.

6.2.5. Inhalation exposure of workers

Potential exposure from a volatile PPP decreases with time as the concentration of the active ingredient is reduced, either by absorption into the plant, degradation, or loss to the environment. Although in many cases inhalation exposure will contribute less to total potential exposure than that by the dermal route, 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./hr inhaled] = Application rate [kg a.s./ha] x Task Specific Factor [ha/hr x 10^{-3}]

The Task Specific Factors can be used in the first tier of the exposure and risk assessment, have been estimated for a small set of exposure data for harvesting of ornamentals and re-entry of greenhouses about 8-16 hours after specific applications; Task Specific Factors are as set out in Table 15.

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

Task	Task Specific Factor (ha/hr x 10^{-3})
Cutting (e.g. ornamentals)	0.1
Sorting and bundling (e.g. ornamentals)	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 8 hours for activities such as harvesting, cutting, sorting etc. and 2 hours for crop inspection or irrigation activities.

This approach may be used for non-volatile and moderately volatile pesticides, where levels of inhalation exposure (vapour and dust) would be 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.

For uses other than ornamentals no inhalation Task Specific Factors are available.

7. Resident and bystander exposure

It is noted that the dataset available for assessing bystander and resident exposure is rather limited, being based on few studies only, some of which performed in the 1980's; furthermore, some of the 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 should be considered (EFSA, 2010):

1. Spray drift (at the time of application)
2. Vapour (may occur after the plant protection product has been applied)
3. Surface deposits
4. Entry into treated crops

Summing all the exposure pathways, each one being conservative, 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.

In the opinion of the PPR Panel (EFSA, 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 and Bell (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 the 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 UK for assessing bystander and resident exposure. A calculator was prepared, which allows estimating the mean, 25th, 75th and 95th centile drift and exposure values for specific scenarios.

In the table below data from the BREAM calculator and the scenarios investigated are reported.

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

BREAM Calculator input	Value	Notes
Nozzle type	FF03110	Conventional flat fan nozzle, only data set 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 metre boom. Further upwind passes could possibly contribute additional drift, but the wind conditions will not be identical and the additional contribution is from including more upwind nozzles or passes is relatively small.
Boom height	0.7 metres	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 upper end of the current "average" in UK based on expert opinion (i.e. 3.5 m/s hence 12.6 km/h). A 2004 UK survey showed that between 15-20% 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./litre spray	Used to generate unit values which can be adjusted by product specific values.

BREAM Calculator input	**Value**	**Notes**
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 UK Code of Practice.
Bystander type	Child and Adult	Data collected on adult and child mannequins. Adult ones were 1.87 m tall, and child ones were 1.03 m (i.e. about median height for 4 years old)
Exposure route	Dermal and Inhalation	
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)	
	Children 1.90 m^3/h	The body weight assumed in this Guidance is 10 kg, which is representative of children around 1 year old. Therefore, to be compatible with this bodyweight an average high activity breathing rate of 0.190 m^3/hour/kg bw should be used, and the rate per hour becomes 0.190 m^3/hour/kg bw x 10 kg = 1.90 m^3/h.
	Adults 2.4 m^3/h,	i.e. 0.04 m^3/h/kg bw x 60kg
	Residents (daily average inhalation rate)	
	Children 0.45 m^3/h,	The body weight assumed in the Guidance is 10 kg, which is representative of children around 1 year old. Therefore, to be compatible with this bodyweight an average breathing rate of 1.07 should be used, and the rate per hour becomes 1.07 m^3/day/kg bw x 10 kg bw / 24 hours = 0.45 m^3/h.
	Adults 0.575 m^3/h,	i.e. 0.23 m^3/kg bw/day x 60 kg bw/24h.
Distance from source	2 metres	Considered to represent realistic worst case distance, for example could represent a sprayer operating at field edge with resident/bystander in garden separated from field by 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 litres/ha which is 12 mL/m^2, and at the spray concentration of 1 g/litre, assuming above, this would deliver 120 g/ha or 12 mg/m^2. The model predicts well 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.

For estimating exposure from surface deposits, the data for application in orchards are taken from the drift data from Ganzelmeier; for arable crops, the data are from the BREAM project.

Dermal and oral absorption percentages should be taken from the toxicological evaluation. For the dermal absorption percentage to be used for bystander and resident exposure assessment, for contact with spray solution 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.

An adjustment for light clothing for residents and bystanders is proposed: assuming that the trunk is covered and this represents 36% of the body surface area, and that the clothing gives 50% protection (in line with the EUROPOEM I report for clothes), this would result in a reduction of 18% for adults, and 18% for children (trunk represents 35.7% of the body surface area). This adjustment is considered in addition to the adjustments taken into account in the TC values.

The possibility of refining the exposure assessment considering an increase of the distance from the source up to 5 and 10 meters is given in the calculator.

7.1. 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 exposures does not seem appropriate whereas consideration of summing the means is reasonable. On this basis, both the 75th and mean values need to be calculated for each residential exposure (currently only available for spray drift and drift deposit), but only the latter are summed (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 where there is some uncertainty).

7.1.1. Spray drift

For arable crops, it was agreed that the BREAM data provide a better estimate of exposure and more representative of modern practices than the Lloyd & Bell data. The BREAM data, in addition, provide drift data for children (using mannequins representative of 4 years-old children). The BREAM results do not provide values for upward spraying.

For orchard crops and vines, the most appropriate dataset is that for nozzles applying 470 litres/ha, from a 1987 report by Lloyd et al.. This gave the highest exposures in that report: no adjustment is proposed to the exposure values for orchard crops and vines, since the measurements in the 1987 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 orchard edge spray is only directed into the crop) makes it less likely that a resident would be much closer than 8 m to the spray source of a passing sprayer. Moreover, the 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.

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

The dermal and inhalation exposures (75^{th} percentile and mean values) are as shown in Table 16 and 17.

Table 16: Dermal and inhalation exposures for residents (75th centile from data on potential dermal and inhalational exposures, with correction for incomplete dermal absorption using the dermal absorption percentage for the in use dilution of the PPP) (adapted and amended from EFSA, 2010)

	These values are the 75th Percentiles for Residents (assuming average breathing rates for inhalation exposures)			
Method of Application/Distance from sprayer	**Dermal (ml spray dilution/person)**		**Inhalation (ml spray dilution/person)**	
	Adult	**Children**	**Adult**	**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*				
2-3 m	5.63	1.689	0.0021	0.00164
5 m	5.63	1.689	0.0021	0.00164
10 m	5.63	1.689	0.0021	0.00164

*the only available values are for the 8 m distance from broadcast air assisted sprayer in orchard; the same value is used for 2-3, 5 and 10 m.

Table 17: Dermal and inhalation exposures for residents (mean data on potential dermal and inhalational exposures, with correction for incomplete dermal absorption using the dermal absorption percentage for the in use dilution of the PPP) (adapted and amended from EFSA, 2010)

	These values are the mean values (assuming average breathing rates for inhalation exposures)			
Method of Application/Distance from sprayer	**Dermal (ml spray dilution/person)**		**Inhalation (ml spray dilution/person)**	
	Adult	**Children**	**Adult**	**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* 2-3m 5m 10m	 3.68 3.68 3.68	 1.11 1.11 1.11	 0.00170 0.00170 0.00170	 0.00130 0.00130 0.00130

*the only available values are for the 8 m distance from broadcast air assisted sprayer in orchard; the same value is used for 2-3, 5 and 10 m.

It is noted that no data are available for manual application. The WoG proposes to use the same data as for vehicle application as a first tier assessment. 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 be based on:

Dermal exposure: adults 0.47 mg, children 0.26 mg; Note for these examples 1 mg = 1mL
Inhalation exposure: adults, breathing 0.575 m^3/h, 0.0001 mg; and children, breathing 0.45 m^3/h, 0.00022 mg

For orchard applications Lloyd, Cross, Bell, Berrie & Samuels (1987) provides values measured at 8 metres downwind. This study measured bystander exposure for three application volumes 422, 90 and 34 litres of spray/ha. There is a clear correlation between the levels of bystander exposure increasing with the applied spray volume. It is therefore proposed to use the data from the highest volume.

Dermal exposure = 5.63 mL x 0.3 (child: adult body area) = 1.69 mL
Inhalation exposure= 0.0021 mL x (0.45 child/0.575 m^3/h adult breathing rate) = 0.0016 mL

The values for the average values 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 risk mitigation measure. Corresponding safety instructions are then necessary on the label: an adjustment of drift based on 50% reducing nozzles was agreed by the WoG, considering 50% a reliable factor from experimental data showing from 50% up 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. Therefore, further drift measurements are required for implementation of drift reducing nozzles considering > 50% drift reduction.

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

- adult value of 15 µg/m^3 x 0.23 m^3/day/kg x 60 kg = 3.45 µg/day/kg x 60 kg = 207 µg/day;
- child value of 15 µg/m^3 x 1.07 m^3/day/kg x 10 kg = 16.05 µg/day/kg x 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 air of 1 µg/m^3 and daily average breathing rates as reported in Table 4, resulting in:

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

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

7.1.3. Surface deposits

Dermal exposure from surface deposits based on spray drift should be the following (EFSA, 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, another percentile could be considered for risk refinement)

- TTR = Turf Transferable Residues (%) (a default value of 5 % derived from transferability studies with wet hands is recommended by US EPA, 2001).
- TC = Transfer Coefficient (cm^2/hour) (default values of 7300 cm^2/hour for adults and 2600 cm^2/hour for children are recommended);
- H = Exposure Duration (hours) (a default value of 2 hours is recommended by US EPA, 2001).
- DA = Dermal Absorption (%)
- BW = Body Weight (kg)

Exposure from surface deposits for children aged less than 3 years should be calculated as:

Dermal exposure + Hand to mouth transfer + Object to mouth transfer

Children's Hand to Mouth Transfer

SOE_H = (AR x D x TTR x SE x SA x Freq x H x 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, another 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 (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 Camman and colleagues on the fraction of pesticide extracted by saliva from hands (Camman 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/hour) (for short term exposures the value of 9.5 events/hour is recommended, this is the average of observations ranging from 0 to 70 events/hour (US EPA, 2001)
- H = Exposure Duration (hours) (a default value of 2 hours is recommended by US EPA, 2001).
- OA = Oral Absorption (%)
- BW = Body Weight (kg)

Children's Object to Mouth Transfer

SOE_O = (AR x D x DFR x IgR x 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 (%)
- DFR = Dislodgeable Foliar Residues (%) (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 Tables 18, as appropriate.

Different risk mitigation measures for the assessment of surface deposits can be applied at MS level. For example safety distances > 2 m or > 3 m, respectively can be used for the risk assessment (values are only available for data from Rautmann). Furthermore, drift reducing nozzles (e.g. 50 %, 75 % or 90 %) can be considered as risk mitigation measure (c.f. 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). Corresponding safety instructions are necessary on the label.

Table 18: Ground sediments in % of the application rate calculated on the basis of the median values

	Field crops [1]		**Fruit crops, early stages** [2]		**Fruit crops, late stages** [2]		**Grapes** [2]		**Hops** [2]	
	mean	75^{th} perc.	median	77^{th} perc.	median	77^{th} perc.	median	77^{th} perc.	median	77^{th} perc.
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

[1] from BREAM
[2] from Ganzelmeier/Rautmann

For the ground deposits in field crops, the BREAM data allow for the most conservative assessment.

Table 18 bis	**BREAM data Ground deposits (the scenario modelled has a field rate of 12 mg/m² and this is used to calculate the percentages)**		
Method of Application/Distance from sprayer	95th Percentile (%)	75th Percentile (%)	Mean (%)
Arable/ground boom sprayer			
2 m	8.5%	5.6%	4.1%
5 m	3.5%	2.3%	1.8%
10 m	1.9%	1.3%	1.0%
For drift reducing technology giving at least 50% reduction these figures can be multiplied by 50% As for downward spraying, BREAM data were applied			

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 applications. Further refinements could be considered based on new data. Dust drift for in furrow applications are considered to be negligible.

7.1.4. Entry into treated crops

Entry into treated crops considers exposure resulting from activities like walking in treated field for the adult.

The method used should be the same as for workers, with the same DFR and the general TC for inspection activities, and with 15 min. exposure. For children, all the pathways of exposure to surface deposits are relevant. For adults, object-to-mouth and hand-to-mouth transfer of surface deposits are considered negligible, and can be ignored. For entry onto treated lawns (2 hours inhalation), data are available from adults. For children a ratio based on different surface area of about 0.3 was considered (EFSA 2004); exposures should be calculated as for surface deposits (see above) but taking the deposition percentage as 100%.

For turf treatments the calculation of exposure to drift fallout is not relevant when bystanders/residents will be exposed when entering directly treated areas: the exposure calculation should consider 100% surface deposit for people directly entering treating lawns and parks.

7.2. 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 centile values derived from the underpinning datasets. However, the four estimated exposures will be kept separated as, based on the available data, the WoG considers unlikely and not realistic that all the different exposures from the different pathways will occur contemporarily in the case of bystanders using a probability of 95 %.

For surface deposits, the transfer coefficients should be replaced with 14500 cm^2/hour for adults and 5200 cm^2/hour for children (short term exposure - 15 min, recommended by US EPA), and the frequency of infant hand to mouth activity should be 20 events/hour (95th centile of the range of values from 0 to 70).

For exposure through treatment of crops, four pathways of exposure should be considered, and the potential exposures for each relevant pathway summed:

7.2.1. Spray drift

The exposures from spray drift should be taken as:

Dermal exposure x 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 as shown in Table 19.

Table 19: Dermal and inhalation exposures for bystanders (95th centile) (adapted and amended from EFSA, 2010).Using the BREAM calculator, the values for <u>arable crops</u> in Table 19 should be based on:

Table 19	**These values are the 95th Percentiles for Bystanders (assuming high breathing rates for inhalation exposures)**			
Method of Application/Distance from sprayer	Dermal (ml spray dilution/person)		Inhalation (ml spray dilution/person)	
	Adult	Children	Adult	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*				
2-3 m	12.9	3.87	0.0044	0.0035
5 m	12.9	3.87	0.0044	0.0035
10 m	12.9	3.87	0.0044	0.0035

*the only available values are for the 8 m distance from broadcast air assisted sprayer in orchard; the same value is used for 5 and 10 m.

Dermal exposure: adults 1.21 mg, 10 kg children 0.59 mg (for this e.g. mg = mL).
Inhalation exposure: adults at 2.4 m^3/h 0.0051 mg, children at 1.9 m3/h 0.00112 mg]. Note as before, for this specific example 1mg = 1 mL.

For <u>orchard</u> applications Lloyd, Cross, Bell, Berrie & Samuels (1987) provides values 95th centile dermal 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 over both adult and child heights child values can be estimated as follows:

Dermal = 12.9 mL x 0.3 (child: adult body area) = 3.9 mL
Inhalation = 0.00435 mL x (1.9 child/2.4 adult) = 0.0034 mL

7.2.2. 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 high intensity hourly inhalation rate, according to the volatility of the active substance.

For moderately volatile compounds (vapour pressure ≥ 0.005 Pa and < 0.01 Pa), exposures should be calculated assuming a default concentration in air of 15 µg/m^3 and high intensity hourly inhalation rate resulting in exposures of 9.0 µg/15 min for adults, and 7.125 µg/15 min for children <3 year old.

For compounds with low volatility (vapour pressure <0.005 Pa), exposures should be calculated assuming a default concentration in air of 1 µg/m^3 and high intensity hourly inhalation rate resulting in exposures of 0.6 µg/15 min for adults, and 0.475 µg/15 min for children <3 year old.

7.2.3. Surface deposits

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

SEB_D = (AR x D x TTR x TC x H x 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, another 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 (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/hour) (default values of 14500 cm^2/hour for adults and 5200 cm^2/hour for children are recommended;
- H = Exposure Duration (hours) (a default value of 0.25 hours is recommended by US EPA, 2001).
- DA = Dermal Absorption (%)
- BW = Body Weight (kg)

Exposure from surface deposits for children aged less than 3 years should be calculated as:

Dermal exposure + Hand to mouth transfer + Object to mouth transfer

Children's Hand to Mouth Transfer
SOE_H = (AR x D x TTR x SE x SA x Freq x H x 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 (%)
- 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 (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 Camman and colleagues on the fraction of pesticide extracted by saliva from hands (Camman 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/hour) (for short term exposures the value of 20 events/hour is recommended, this is the 95th percentile of observations ranging from 0 to 70 events/hour (US EPA, 2001)
- H = Exposure Duration (hours) (a default value of 0.25 hours is recommended by US EPA, 2001).
- OA = Oral Absorption (%)
- BW = Body Weight (kg)

Children's Object to Mouth Transfer

SOE_O = (AR x D x DFR x IgR x 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 (%)
- DFR = Dislodgeable Foliar Residues (%) (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 MS level. For example safety distances > 2 m or > 3 m, respectively can be used for the risk assessment (values are only available for data from Rautmann). Furthermore, drift reducing nozzles (e.g. 50 %, 75 % or 90 %) can be considered as risk mitigation measure (c.f. 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). Corresponding safety instructions are necessary on the label.

Table 20: Ground sediments in % of the application rate calculated on the basis of the 95th/90th percentile values

	Field crops [1)]	**Fruit crops, early stages** [2)]	**Fruit crops, late stages** [2)]	**Grapes** [2)]	**Hops** [2)]
	95th perc.	90th perc.	90th perc.	90th perc.	90th perc.
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

1) from BREAM
2) from Ganzelmeier/Rautmann

For products applied as granules the dermal exposure, hand to mouth and object to mouth transfers are calculated with coefficients with values 1/5th of the values given above. Drift from agricultural applications of granules should be assumed to be 3% for broadcast applications ('worst case'). Dust drift for in furrow applications are considered to be negligible.

7.2.4. Entry into treated crops

For entry into crops, only dermal exposure needs be considered. Use the same method and values for DFR and the general transfer coefficient as for workers, with an assumption of 15 minutes exposure per day.

For entry onto treated lawns, exposures should be calculated as for surface deposits (see above) but taking the deposit (% of application rate) as 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

(To be inserted)

RECOMMENDATIONS

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

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APPENDICES

APPENDIX A. CIPAC FORMULATION CODES

(Catalogue of pesticide formulation types and international coding system, Technical Monograph n°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)

APPENDIX B. EXAMPLES

Example Operator exposure *(To be inserted)*

APPENDIX C. 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 multiple application factor (MAF).The MAF is a function of the number of applications, application interval, and decline of residues, typically expressed as a DT50 assuming first order kinetics (single first order, SFO-DT50). Equations are presented for calculation of a MAFm for average residue levels and of a MAF90 for 90th percentile residue levels
(GD on birds and mammals, http://www.efsa.europa.eu/en/efsajournal/pub/1438.htm).

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

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

With:
k = ln(2)/DT50 (rate constant)
n = number of applications
i = application interval (d)
By forming the limit value lim n → ∞ of the equation above, the term e-nki becomes zero and a "plateau" MAFm for an infinite number of applications can be calculated.

APPENDIX D. DT50 (TIME REQUIRED FOR 50% DISSIPATION OF THE INITIAL CONCENTRATION) VALUES FOR PESTICIDE ACTIVE SUBSTANCES (FROM WILLIS AND MC DOWELL, 1987)

A.s.	DT50
2,4-D	3.0
2,4-D	2.4
2,4-D	1.1
Acephate (SP)	1.7
Acephate (SP)	8.2
Aldrin (EC)[e]	1.7
Avermecin B_1	1.5
Azinophosmethyl	2.0
Benomyl (WP)	6.0
Benomyl (WP)	7.2
Carbaryl	1.4
Carbaryl (EC)	1.2
Carbaryl (liquid)	29.5
Carbaryl (WP)	25.4
Carbaryl (WP)	7.4
Carbaryl (WP)[f]	1.3
Carbaryl (XLR)	1.5
Carbofuran	3.2
Carbofuran (EC)	1.1
Carbophenothion (EC)	7.0
Carbosulfan (EC)	2.4
Chlordane (WP)	2.3
Chlordimeform (EC)[e]	0.7
Chlorpyrifos (EC)	0.7
DDT (EC)	1.6
DDT (EC)	9.5
Deltemethrin	7.7
Demeton	8.8
Dialifor	17.0
Diazinon (E)	2.5
Diazinon (EC)	1.2
Diazinon (EC)	0.7
Diazinon (WP)	0.8
Dieldrin	2.7
Dieldrin (D)	4.2
Dieldrin (EC)	6.8
Diflubenzuron (WP)	25.0
Dimethoate	2.5

A.s.	DT50
Dimethoate (EC)	2.2
Dimethoate (LC)	3.1
Dimethoate (LC)	2.7
Dimethoate (LC)	0.9
Endosulfan	2.9
Endosulfan (EC)	1.0
Endosulfan (EC)	4.7
Endosulfan (WP)	4.9
Endosulfan (WP)	3.6
Endrin (D)	1.0
EPN	7.0
EPN (EC)	1.4
EPN (EC)	1.1
EPN (EC)	0.8
EPN (ULV-oil)	0.6
Ethion (EC)	7.9
Ethion (WP)	5.8
Ethion (WP)	17.0
Ethyl parathion	1.6
Ethyl parathion (EC)	0.7
Ethyl parathion (EC)	0.7
Ethyl parathion (EC)	1.0
Ethyl parathion (EC)	6.9
Ethyl parathion (WP)	1.5
Ethyl parathion (WP)	4.4
Ethyl parathion (WP)	1.2
Ethyl parathion (WP)	1.8
Ethyl parathion (WP)	3.3
Fenitrothion (EC)	2.6
Fensulfothion (EC)	2.7
Fensulfothion (EC)	3.3
Fenthion (EC)	2.4
Fenvalerate (EC)	9.5
Heptachlor	1.7
Malathion (D)	0.8
Malathion (D)	1.0
Malathion (D)	1.4
Malathion (D)	2.9

A.s.	DT50
Malathion (EC)	0.7
Malathion (EC)	1.7
Malathion (EC)	6.8
Malathion (WP)	1.4
Malathion (WP)	1.5
Malathion (WP)	5.8
Methamidophos	1.7
Methidathion (EC)	0.5
Methidathion (ULV-oil)	0.6
Methomyl	2.5
Methomyl (EC)	0.4
Methomyl (liquid)	0.5
Methomyl (liquid)	0.5
Methomyl (liquid)	0.7
Methomyl (ULV-oil)	0.7
Methomyl (WP)	1.7
Methomyl (WP)	0.8
Methomyl (WP)	1.2
Methoxychlor (WP)	6.3
Methylparathion	1.0
Methylparathion (E)	13.0
Methylparathion (E)	2.9
Methylparathion (E)	2.0
Methylparathion (E)	1.2
Methylparathion (EC)	0.5
Methylparathion (EC)	0.5
Methylparathion (EC)	0.5
Methylparathion (EC)	0.4
Methylparathion (EC)	0.1
Methylparathion (EC)	1.1
Methylparathion (EC)	0.6
Methylparathion (EC)	1.0
Methylparathion (EC)	1.6
Methylparathion (EC)	0.6
Methylparathion (ULV)	0.6
Monocrotophos	3.1
Monocrotophos (EC)	3.4
Monocrotophos (WM)	1.3

A.s.	DT50
Oxamyl (EC)	0.7
Permethrin (EC)	3.0
Permethrin (WP)	4.9
Phenthoate	1.5
Phenthoate	3.1
Phenthoate	3.6
Phorate (EC)	1.4
Phosmet (WP)	3.2
Phosphamidon	4.0
Phoxim (EC)	1.5
Phoxim (EC)	2.1
Profenofos (EC)	1.2
Sulprofos (EC)	0.8
Sulprofos (ULV-oil)	0.6
Toxaphene (EC)	1.6

The Willis & McDowell data set reports 130 half-life values for 48 compounds. The 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 the data is such that the total residue values are sometimes shorter than the dislodgeable residue half-life value

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

The ARS data set reported foliar half-life 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 HL
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	10000
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

AI Name	Foliar HL
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
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, butoxyehtanol ester	9
Diclofop-methyl	8
Dicloran	4
Dicofol	4

AI Name	Foliar HL
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
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

AI Name	Foliar HL
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
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

AI Name	Foliar HL
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
Phosphamidon (ANSI)	5
Phostebupirim	3

AI Name	Foliar HL
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
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

AI Name	Foliar HL
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

AI Name	Foliar HL
Trichlorfon	3
Tridiphane (ANSI)	8
Triethylamine triclopyr	15
Triflumizole	3
Trifluralin (ANSI)	3
Triflusulfuron-Methyl	3
Triflusulfuron-Methyl	3
Triflusulfuron-Methyl	3
Triforine (ANSI)	5
Uniconazole (ANSI)	3
Vernolate	2

APPENDIX F. EXPOSURE CALCULATION SPREADSHEET

Available at:

http://www.efsa.europa.eu/en/consultations/call/140401.htm

APPENDIX G. 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 (Kissel et al 1996). A default value for inhalation exposure should be estimated assuming a total inhalation dust exposure of 98.6 mg/m^3 (Nieuwenhuijsen et al 1998).

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

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

- for acute assessment the highest initial 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 H. COMPARISON OF TC VALUES USED IN THE GUIDANCE WITH US EPA

Crop	Nature of task	Main body parts in contact with foliage	Transfer Coefficient (cm^2/hr) total potential exposure	Transfer Coefficient (cm^2/hr) assuming arm, body and legs covered (bare hands)	Transfer Coefficient (cm^2/hr) Covered body and gloves	Applicable to the following crops	EUROPOEM II Details	Actual EUROPOEM value used in calculator	EPA - TC	Task details
Vegetables	Reach / Pick	Hand and body	5800	2500	580	· Brassica vegetables · Fruiting vegetables · Leaf vegetables and fresh herbs · Legume vegetables · Bulb vegetables	75 th = 2,200 cm2/hr hands 75 th = 3,600 cm2/hr body Hands and body = 5800 cm2/hr 10 fold reduction for protective clothing Total = 2560 cm2/hr approx 2500 With gloves same method = 580 cm2/hr (own calculation)	2500	4200 1100 1400 1100 4200	Hand harvesting Hand harvesting (Peppers, Tomato) Hand harvesting Hand harvesting Hand weeding
Tree fruits	Search / Reach / Pick	Hand and body	22500	4500	2250	· Citrus · Cane fruits · Oilfruits · Pome fruits · Stone fruits	75 th = 2500 cm2/hr hands 75 th = 10000 cm2/hr body 90 th = 20000 cm2/hr body Hands and body = 22500 cm2/hr (90th for body as the database is small) Total = 4500 cm2/hr approx 4500 With gloves same method = 2250 cm2/hr (own calculation)	4500	1400 1400 1400 3600 3600	Hand harvesting Hand harvesting Hand harvesting Thinning fruit Thinning fruit

Crop	Nature of task	Main body parts in contact with foliage	Transfer Coefficient (cm²/hr) total potential exposure	Transfer Coefficient (cm²/hr) assuming arm, body and legs covered (bare hands)	Transfer Coefficient (cm²/hr) Covered body and gloves	Applicable to the following crops	EUROPOEM II Details	Actual EUROPOEM value used in calculator	EPA - TC	Task details
						· Tree nuts			1400	Hand harvesting
Grapes[1]	Harvesting	Hand and body	30000	10100	no justified proposal possible				10100	Hand harvesting (19300 Harvesting, Mechanically-assisted)
Strawberries	Reach / Pick	Hand and forearm	3000	3000	750	· Berries and other small fruit, low	arithmetic means = 2500 cm2/hr hands, Hands and forearms = 3670 cm2/hr - adjusted to 3000 cm2/hr as value wash high (? inexperienced pickers) With gloves assuming 10 fold reduction = 750 cm2/hr (own calculation)	3000	1100	Hand harvesting
Ornamentals	Cut / Sort / Bundle / Carry	Hand and body	14000	5000	1800	· Ornamentals and Nursery	75 th = 4,000 cm2/hr hands 90 th = 10,000 cm2/hr body Hands and body = 14000 cm2/hr 10 fold reduction for protective clothing Total = 5400 cm2/hr approx 5000 With gloves same method = 1800 cm2/hr (own calculation)	5000	4800 (Floricultur e) 230 (Ornamenta ls)	Hand harvesting
Golf course, turf or other sports lawns	Maintenance	Hand and body	5800	2500		580			3700	Maintenance

Crop	Nature of task	Main body parts in contact with foliage	Transfer Coefficient (cm^2/hr) total potential exposure	Transfer Coefficient (cm^2/hr) assuming arm, body and legs covered (bare hands)	Transfer Coefficient (cm^2/hr) Covered body and gloves	Applicable to the following crops	EUROPOEM II Details	Actual EUROPOEM value used in calculator	EPA - TC	Task details
General	Inspection, irrigation	Hand and body	3600	1100	no justified proposal possible	· Cereals · Grassland and lawns · Hops · Oilseeds · Root and tuber vegetables · Sugar plants			1100 6700 640 1100 210 8800	Scouting Maintenance Scouting Scouting Scouting Hand harvesting (sugar cane)

GLOSSARY AND ABBREVIATIONS

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 in this report 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.

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

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

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

Drift (expressed as % 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.

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.

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

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.

Operators: Persons who are involved in activities relating to the application of a plant protection product (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 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.

Personal protective equipment: 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.

Residents: 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 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/hr x 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.

Work wear (operator): Normal work wear 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.