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ACROPOLIS

Aggregate and Cumulative Risk Of Pesticides: an On-Line Integrated Strategy

SEVENTH FRAMEWORK PROGRAMME

Deliverable 3.1 Report describing data structures and data availability for non-dietary exposure.

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Summary

There are many sources of non-dietary exposure to pesticides, with a wide range in the quantity and quality of data available in the open literature or available to regulators. Currently the data sources are richest in the areas dealing with occupational exposure, such as with PPPs and biocides, and poorest with exposure scenarios for the general population to products used in the home or garden, where there are many aspects to the use scenarios depending on the behaviour of individuals and the range of products available.

The models used for predicting PPP exposure are based on empirical data with coverage of a relatively small number of scenarios. The models derive surrogate exposure values using different percentiles such as 75th or 95th for inhalation and dermal (potential and/or actual) exposures. The most commonly used models are the UK POEM and the German model, which have similar structures. Developing models are the southern Europe greenhouse model, and updated German model adding recent data generated by industry. The FP7 project BROWSE is developing conceptual models for Occuaptional exposure to PPPs. In the USA the AHED model has replaced the PHED model. Data sets for exposure are available in the southern Europe greenhouse model and also the EUROPOEM database. Limited data sets exist for exposure of PPP users for amenity and amateur uses. In terms of PPP usage for the different sectors, there are good datasets for use of professional PPPs in agriculture, although this varies between the countries, being most comprehensive for the UK. Limited use data exists for amenity PPPs and no data are available for amateur PPPs.

There are a wide range of biocide models, although the most commonly used model by regulators is BEAT , which is a probabilistic task-based model, and consequently very different to the PPP models for PPPs. The model also allows the user to use their own data to be fed into the model allowing comparison to be made with the data present in the database. By using a task based approach there is a relatively broad coverage of scenarios compared to the empirical models. The datasets for exposure within BEAT can be extracted for use in ACROPOLIS,

The availability of data for use or exposure of compounds used by professional users or the general public is poor or non-existent. For use of products such veterinary medicines (by professional and amateur users) and pharmaceuticals, which are known to contain compounds commonly used as PPPs there are no known data available other than general sales data.

Abbreviations

ADE	Actual dermal exposure
ADI	Admissible daily intake
AHETF	Agricultural Handler Exposure Task Force
a.i.	Active ingredient
a.s.	Active ingredient
AOEL	Acceptable Operator Exposure Level
ARfD	Acute reference dose
BROWSE	Bystanders, Residents, Operators and WorkerS Exposure models for PPP
DFR	Dislodgeable foliar residue
ECPA	European Crop Protection Association
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
ha	Hectare
LAI	Leaf area index
NOAEL	No observable adverse effect level
OECD	Organisation for Economic Cooperation and Development
PDE	Potential dermal exposure
POEM	Predictive Operator Exposure Model
PPE	Personal protective equipment
PPE	Personal protective equipment
PPP	Plant protection products
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical substances
RPE	Respiratory protective equipment

Glossary of terms (from BROWSE project and EFSA 2010 project)

General terms

Active ingredient (OECD, 1997)	That ingredient of a pesticide to which the pest control effects of the pesticide are primarily attributed.
Active substance	Any substance or micro-organism (including a virus), that has a general or specific action against harmful organisms or on plants, parts of plants or plant products (the term 'active ingredient' is often used to mean the same thing).
Actual dermal exposure (OECD, 1997)	The amount of pesticide coming into contact with bare (uncovered) skin and : the fraction transferring through protective and work clothing or via seams to the underlying skin, and which is therefore available for percutaneous absorption.
Aggregate exposure	A sum of the exposure from all pathways and routes for a single chemical (see aggregate risk)
Aggregate risk	The risk associated with all pathways and routes of exposure to a single chemical.
Analyte (OECD, 1997)	Chemical moiety (pesticide or metabolite) that is the subject of chemical analysis.
AOEL (European Commission, 2006)	The maximum amount of active substance to which the operator may be exposed without any adverse health effects. The AOEL is expressed as milligrams of the chemical per kilogram body weight of the operator.
Breakthrough (OECD, 1997)	The passage of a chemical through a sampling medium (e.g. air sampling tube) or penetration of a chemical through protective clothing or devices (e.g. gloves, respirator).
Breathing zone (OECD, 1997)	The area around the nose and mouth from which air is inhaled.
Bystander (EFSA 2010)	Person who is 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; and who take no action to avoid or control exposure.
Concentration (OECD, 2003)	Amount of a material or agent dissolved or contained in unit quantity in a given medium or system.
Cumulative exposure	The risk deriving from combined exposure to compounds that share the same mode of action or that have similar effects but by different modes of action (see cumulative risk).
Cumulative risk (EFSA 2008)	The risk associated with all pathways and routes of exposure to compounds that share the same mode of action or that have similar effects but by different modes of action.
Cycle (OECD, 1997)	A recurring sequence composed of one mixing, one loading and one application event.
Dermal absorption (OECD, 1997)	Movement of a pesticide into and through the skin; includes that taken up into the systemic circulation and that retained in the skin compartment.
Descriptive model	A model (mostly) based on empirical knowledge and data sets, in which the relation between input and output variables is statistically shown. (Related term: Empirical modelling)

Dose (OECD, 1997)	The amount of a pesticide systemically available.
Drift (OECD, 1997)	The movement of pesticide by wind or air currents to non-target areas.
Exposure (OECD, 1997)	A condition of oral, dermal, respiratory or ocular contact between a person and a pesticide.
Exposure assessment (OECD, 2003)	Evaluation of the exposure of an organism, system or (sub) population to an agent (and its derivatives). Exposure Assessment is the third step in the process of Risk Assessment.
Exposure scenario (OECD, 2003)	A set of conditions or assumptions about sources, exposure pathways, amount or concentrations of agent(s)involved, and exposed organism, system or (sub) population (i.e. numbers, characteristics, habits) used to aid in the evaluation and quantification of exposure(s) in a given situation.
Extrapolation (OECD, 1997)	Quantitative estimate of values outside the range of measured values.
Formulation (OECD, 1997)	A mixture of an active ingredient with diluents, carriers and other materials to form the packaged product.
Inspirable fraction (OECD, 1997)	That fraction of airborne particulate capable of entering the respiratory tract via the nose and the mouth, so providing a source of absorption into the body, either from direct inhalation or from subsequent oral ingestion.
Label (OECD, 1997)	Any legend, word, mark, symbol or design applied or attached to, included in, belonging to or accompanying any control product.
Limit of detection (OECD, 1997)	The level at which a pesticide can be detected but not quantified for a given analytical procedure.
Limit of quantification (OECD, 1997)	The smallest amount of the pesticide that can be quantified by the analytical method.
Margin of exposure (OECD, 2003)	Ratio of the no-observed-adverse-effect level (NOAEL) for the critical effect to the theoretical, predicted or estimated exposure dose or concentration. (Related term: *Margin of Safety*)
Margin of safety (OECD, 2003)	For some experts the Margin of Safety has the same meaning as the Margin of Exposure, while for others, the Margin of Safety means the margin between the reference dose and the actual exposure dose or concentration. (Related term: *Margin of Exposure*)
Monitoring unit	A measurement of exposure to a worker during one typical work day, which includes all job functions related to pesticide use. (Note: preferred replacement for “replicate”)
Normalisation (OECD, 1997)	A standardised expression of exposure as a function of another variable (e.g. µg/amount active ingredient handled, µg/time, µg/area treated).
Operator (EFSA 2010)	Person who is involved in activities relating to the application of a PPP; such activities include mixing/loading the product into the application machinery, operation of the application machinery, repair of the application machinery whilst it contains the PPP, and emptying/cleaning the machinery/containers after use. Operators may be either professionals (e.g. farmers or contract applicators engaged in commercial crop production) or amateur users (e.g. home garden users).
Passive dosimetry (OECD, 1997)	A method of measuring the amount of pesticide coming into contact with an individual.
Personal monitoring (OECD, 1997)	(see passive dosimetry)
Personal protective	Any device or appliance, which conforms to the appropriate standards, designed

equipment (PPE)	to be worn or held by an individual for protection against one or more health and safety hazards (for example, by impeding the passage of pesticides).
Pesticide (OECD, 1997)	Any substance or mixture of substances intended for preventing or controlling any unwanted species of plants and animals; also includes any substances or mixture of substances intended for use as a plant growth regulator, defoliant or desiccant.
Potential dermal exposure (OECD, 1997)	The total amount of pesticide coming into contact with the protective clothing, work clothing and exposed skin.
Predictive model	A model based on scientific causality and described by a numerical construct. Depending on the quality (and detail) of the model, the reality is reflected to a varying degree. (Related term: deterministic modelling)
Resident (EFSA 2010)	Person who lives, works or attends school or any another 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.
Respiratory protective equipment (RPE)	Any respiratory or breathing apparatus, which conforms to the appropriate standards, designed to prevent or control inhalation exposure to airborne contamination.
Site (OECD, 1997)	A location at which one or more replicates are monitored.
Surrogate data (OECD, 1997)	Exposure data collected for one pesticide that are used to estimate exposure to a similar pesticide.
Validation (OECD, 2003)	Process by which the reliability and relevance of a particular approach, method, process or assessment is established for a defined purpose. Different parties define “Reliability” as establishing the reproducibility of the outcome of the approach, method, process or assessment over time. "Relevance" is defined as establishing the meaningfulness and usefulness of the approach, method, process or assessment for the defined purpose.
Ventilation rate (OECD, 1997)	Breathing rate used for calculating inhalation exposure.
Worker (EFSA 2010)	Person who, as part of his/her employment, enters an area that has previously been treated with a PPP or who handles a crop that has been treated with a PPP.

Terms related to type of application equipment / method for plant protection products (NPTC, 2010)

Aerial application	Aerial application constitutes the application of pesticides from aircraft (either fixed wing or helicopters) in flight
Air assistance	Air assistance constitutes the use of a fan to carry spray droplets to their intended target
Application as a continuous process	Application of pesticides as a continuous process constitutes the application of pesticide using equipment which is mounted on, attached to or forms a permanent part of a treatment system, for example with conveyors, roller tables and other moving equipment
Boat Mounted Applicators	Boat Mounted Applicators constitute any equipment which applies pesticide and is mounted on, or attached to or forms a permanent part of any boat
Broadcast Sprayers	Broadcast Air Assisted Sprayers constitute any equipment which broadcasts spray droplets by means of an uncontained air stream produced by fan assistance and which carry outwards and upwards from the source of the spray
Dipping	Dipping involves the immersion of material to be treated, or part thereof in a pesticide solution
Downward Air Assistance	Downward Air Assistance involves the use of an enclosed fan generated air stream to assist penetration of the crop canopy
Electrostatically charged	Material to which an electrostatic charge has been intentionally added
Field	Field constitutes any site where possible application is being undertaken
Granule Applicators	Granule Applicators constitute any full width broadcast or placement type equipment which applies pesticide in granule or powder form
Ground Crop Sprayers	Ground Crop Sprayers constitute any equipment of the spray boom type which apply pesticide via a boom operating in an horizontal plane
Hand held applicators	Hand held applicators constitute any equipment either wholly carried by a person or where the pesticide delivery nozzle or outlet is supported directly by the operator
Hydraulic nozzle	A device wherein pressurised liquid is the primary source of energy utilised to produce a spray
Micro-Processor control systems	Computer control systems may include automatic, semi-automatic and electromechanical control systems
Mists and Fogs	Mists and Fogs (including smokes) are particulate clouds having particles of a size range less than 100 microns Volume Median Diameter
Mixer/loader	Mixer/loader includes any individual who is involved in the mixing and/or the loading of pesticides into the tank or hopper of any pesticide application equipment
Mounted Equipment	Mounted Equipment constitutes any pesticide application equipment mounted on, attached to or which forms a permanent part of the prime mover.
Pedestrian controlled equipment	Pedestrian controlled equipment constitutes any equipment which is supported by a mechanical form of carriage controlled by a person who cannot ride in or on the equipment carriage
Prime Mover	Prime Mover constitutes any self propelled vehicle carriage operated by a person who rides in or on the vehicle
Rotary atomiser	A device wherein a rotating solid surface (e.g. cup, disc, wheel or cage) is the primary source of energy utilised to produce a spray
Seed Treatment Equipment	Seed Treating Equipment constitutes any equipment, either mobile or static which applies pesticides to cereal grains, pulses and other small seeds
Spray Trains	Spray Trains constitute any vehicle running on permanent way and to which any equipment which applies pesticide to the track, trackside and / or adjacent areas is mounted, attached, or where such equipment forms a permanent part of the vehicle.

Sprayers	Sprayers constitutes any equipment used to apply sprays having droplets within a maximum and minimum size range described by the British Crop Protection council nozzle classification scheme categories Coarse, Medium and Fine
Sub surface liquid applicators	Any type of machine (excluding pedestrian controlled) designed to apply liquid pesticide below surface level
Trailed Equipment	Trailed Equipment constitutes any pesticide application equipment which is trailed behind the prime mover
Twin-fluid nozzle	A device wherein the movement of gas or vapour is the primary source of energy utilised to produce a spray
Variable Geometry Sprayers	Variable Geometry Sprayers constitute any equipment of the spray bar type which applies pesticide via a boom, the geometry of which may be varied between a horizontal and vertical plane and set in accordance with the spray target
Vehicle Mounted kerb sprayers	Vehicle Mounted kerb sprayers constitute any equipment which is mounted on, fixed to or forms part of any vehicle for the purpose of allowing the application of pesticides to road side kerbs
Wick Applicators	Wick Applicators constitute any equipment which applies pesticides via an impregnated wick or similar device

1. Use and exposure scenarios

The various sources of exposure have been evaluated considering their principal uses, which relates to the development of models used in risk assessment and also to sub groups of the population.

PPPs	Operator exposure	Mixing and loading Applicator Equipment cleaning
	Worker exposure	Re-entry tasks
Biocides	Operator exposure	Mixing and loading Applicator Equipment cleaning
	Worker exposure	Re-entry tasks
Vet Medicines	Operator exposure	Mixing and loading Applicator Equipment cleaning
	Worker exposure	Re-entry tasks
Amateur (Home & Garden)	Operator exposure	Mixing and loading Applicator Equipment cleaning
Consumer products	User exposure	Topical use Ingestion
Bystander	Short term exposure	Activities usually away from the home
Resident	Long term	Activities usually in the home or garden

The existing and developing models have been identified, and a brief summary of the most appropriate models is given in Appendix I. Where data are lacking or there are doubts about the robustness or suitability of existing models, the use of expert elicitation is under consideration.

In addition to the data for the exposure scenarios, supporting data is being sought from retailers and industry. This would include sales data of the various products containing PPPs and data from industry such as ECPA.

Data will also be made available from existing projects such as the EFSA non-dietary exposure project and the FP7 project BROWSE

2. Principal categories of exposure scenarios

2.1 Operator exposure PPPs

Most EU MS tend to use the German model (Lundehn et al. 1992) or UK POEM (Martin 1990) for the applicator exposure. For the mixing and loading exposure the UK POEM has more detailed information on the use of container sizes, missing from the German model. The Dutch model (van Hemmen, 1992) is used in the Netherlands, and has data more applicable to Dutch conditions with greenhouse crops.

The data from the UK POEM and German model have been assessed for quality and many of the more appropriate datasets have been added to the EUROPOEM. This is an Excel spreadsheet, which was hosted on the old EUROPOEM website by the Central Science Laboratory (now Fera) until 2007. The data are reported in the reports for EUROPOEM I (1996) and EUROPOEM II (2002) and reported by van Hemmen (2001 and 2005)

More recently a southern European Greenhouse model has been initiated by industry (ECPA), to overcome some of the data deficiencies in the UK and German models. Access to this data and permission to use it is likely to be possible.

The data is principally potential dermal exposure (PDE) and actual dermal exposure (ADE) data from the use of outer and inner dosimeter dermal dosimeters. Inhalation exposure data is usually available also. Experimental methods usually follow the OECD Guidance Document (OECD, 1997)

Data from North America have been sued to prepare the Pesticide Handlers Exposure Database (PHED, 1992 and 1998)

Systemic exposure data is available in some, typically more modern, datasets in conjunction with dermal exposure, to give some indication of the relationship between PDE or ADE and the absorbed dose. However, to estimate the absorbed dose requires PBPK information for the substance in question and its metabolites which is not always available. Dermal absorption data, which may be affected by the PPP formulation and spray solution, are also not readily available.

In all of the databases/models there are limited data on key factors such as

- Work rates
- Contact rates
- Use of PPE

A summary of available data was prepared (Hamey et al. 2008) as part of an EFSA funded project.

Data will be available from the EFSA project (CT/EFSA/PPR/2010/05) and BROWSE (Grant Agreement No: 265307) during 2011 to provide some of the missing data.

These are all empirical models which can be used to provide point estimates by scaling normalised exposures. Distributions of exposure can be established in some cases, working with existing exposure data. This will allow some probabilistic modelling of variation in exposures.

Need to consider separately

- PPP
- Biocides
- Veterinary medicines

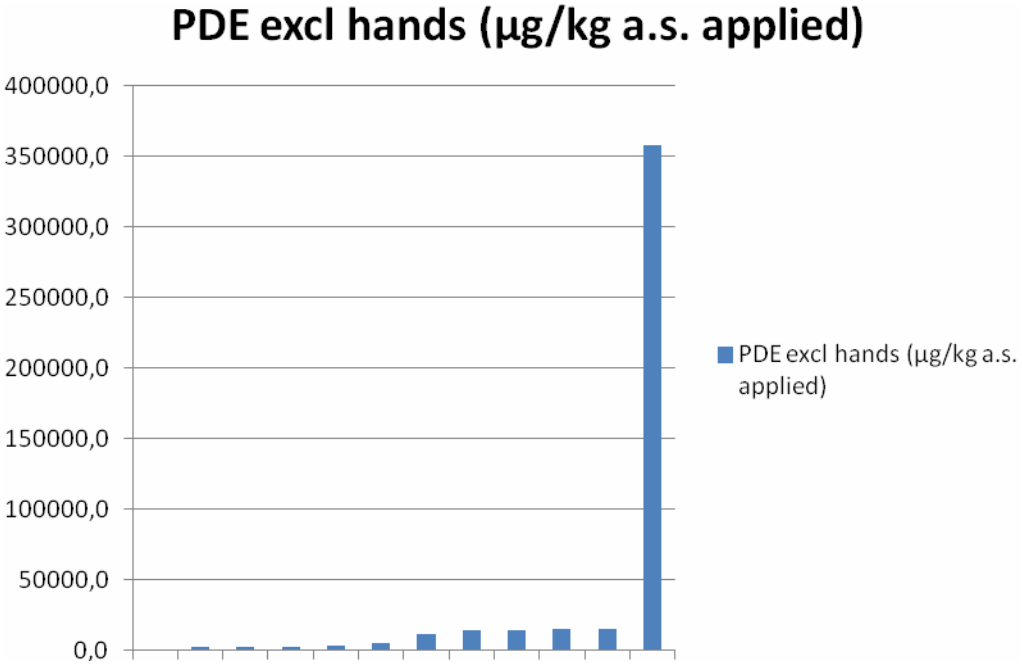
Within the PPP use then consider separately agricultural uses and amenity uses

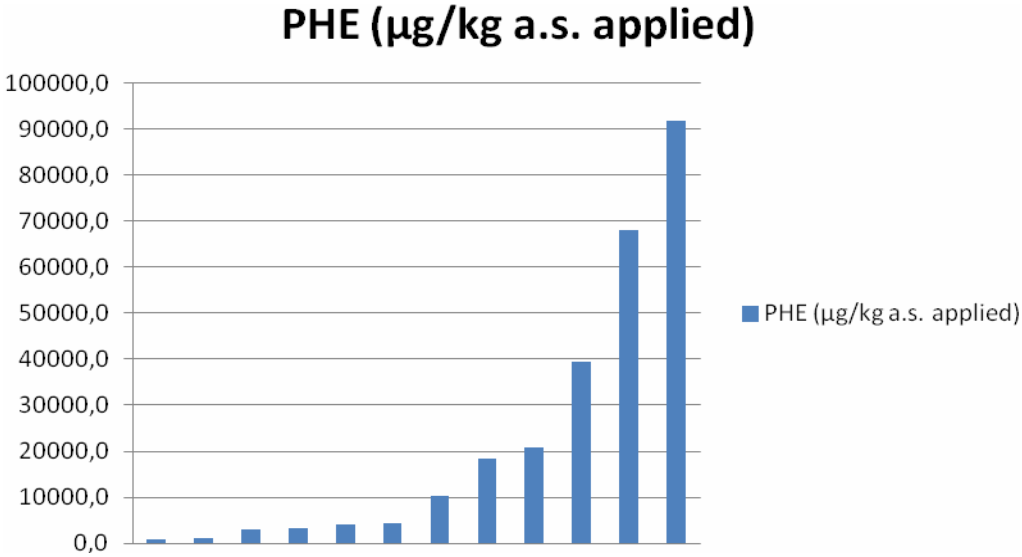
Currently the most suitable data available is form the EUROPOEM spreadsheets

For the purpose of presenting the data structure study 26 has been chosen as an appropriate study, which is for ground boom sprayers

Table 1. Distribution of exposure data from EUROPOEM for M/L/A

Study number	Rep number	PDE excl hands (µg/kg a.s. applied)	ADE excl hands (µg/kg a.s. applied)	PHE (µg/kg a.s. applied)	AHE (µg/kg a.s. applied)
26	1	373.3	5.5	20692.5	19.1
26	2	15568.4	406.4	39576.2	19.3
26	3	5644.4	184.2	1192.6	<LOQ
26	4	358279.2	145.3	10319.7	<LOQ
26	5	2872.7	48.2	68038.7	37.3
26	6	11739.4	265.2	4392.3	<LOQ
26	7	14732.5	292.5	3009.5	<LOQ
26	8	3114.2	96.6	3270.5	688.5
26	9	2290.8	34.1	18381.0	125.3
26	10	2296.4	30.1	877.0	<LOQ
26	11	15235.2	455.5	4027.5	<LOQ
26	12	14440.8	451.2	91818.2	72.6





2.2 Operator exposure Biocides

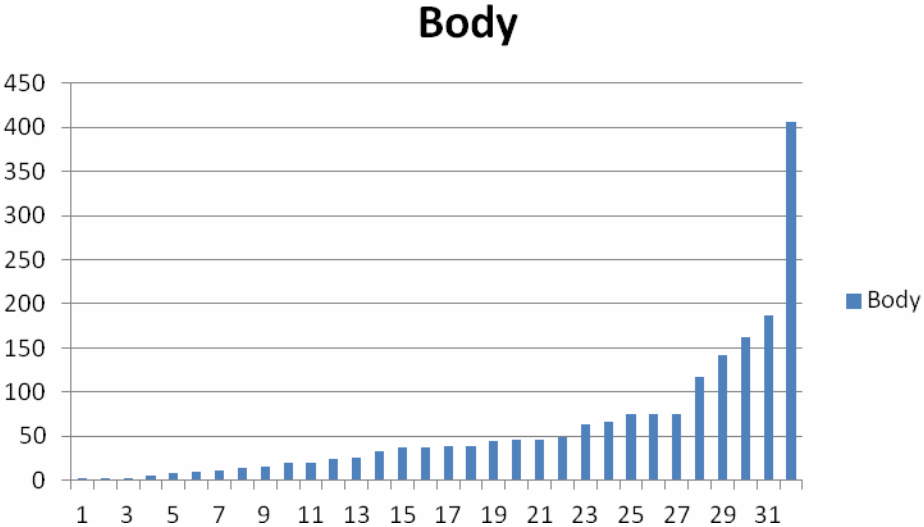
The Bayesian exposure assessment tool (BEAT) is a probabilistic task-based model using datasets available as Technical Notes for Guidance (TNsG, 2008) developed using analysis of the data (Phillips and Garrod 2001) and a conceptual dermal model (Schneider et al., 1999). BEAT compares the process information provided to the evaluator with the data present in the database. The model integrates expert judgment and objective measurements by three model elements: a Bayesian framework, a rule base (expert judgment) and a database with dermal exposure measurements (biocidal products) and contextual information. The model is used during the registration of biocides to estimate worker exposure using exposure data that are available in a number of cases. The data available in the case studies can be extracted from BEAT as an Excel file allowing the data to be used

in ACROPOLIS where appropriate use scenarios are identified. Examples of the data available are shown below.

Example 1: Austrian wood preservatives (water based conazole)

In this simulation study volunteers applied solvent-based paints containing wood preservatives to wooden fences. A multi-factorial design allowed a number of parameters to be varied including the individual's level of experience, the complexity of the surface to be painted (flat vs. lattice) the size of brush and the wind speed. There is considerable uncertainty surrounding the quantity of wood preservative applied , this being difficult of determine from the report. An overall quantity of 7.3 litres for lattice fences and 4.45 litres for flat panels has been assumed.

amount_ appld	bodyld_ lower	bodyld_ upper	duration	handsld_ lower	Handsld _upper	Inhaled _lower	inhaled_ upper
7.3	20.08	20.08	29	12.29	12.29	<LOQ	<LOQ
4.25	14.27	14.27	35	301.7	301.7	<LOQ	<LOQ
7.3	3.1	3.1	54	12.23	12.23	<LOQ	<LOQ
4.25	48.71	48.71	72	1011.59	1011.59	<LOQ	<LOQ
7.3	2.42	2.42	29	5.35	5.35	<LOQ	<LOQ
4.25	74.55	74.55	42	79.08	79.08	<LOQ	<LOQ
7.3	11.49	11.49	27	8.34	8.34	<LOQ	<LOQ
7.3	2.58	2.58	32	21.05	21.05	<LOQ	<LOQ
4.25	45.53	45.53	68	247.2	247.2	<LOQ	<LOQ
7.3	5.86	5.86	31	10.15	10.15	<LOQ	<LOQ
4.25	26.25	26.25	68	194.13	194.13	<LOQ	<LOQ
7.3	23.68	23.68	21	21.08	21.08	<LOQ	<LOQ
4.25	187.55	187.55	87	446.67	446.67	<LOQ	<LOQ
7.3	9.01	9.01	23	8.55	8.55	<LOQ	<LOQ
4.25	75.1	75.1	53	93.75	93.75	<LOQ	<LOQ
7.3	63.71	63.71	27	228.34	228.34	<LOQ	<LOQ
4.25	37.88	37.88	47	77.86	77.86	<LOQ	<LOQ
4.25	405.36	405.36	44	1300.82	1300.82	<LOQ	<LOQ
7.3	20.13	20.13	12	12.35	12.35	<LOQ	<LOQ
4.25	32.97	32.97	46	59.91	59.91	<LOQ	<LOQ
7.3	15.65	15.65	32	6.74	6.74	<LOQ	<LOQ
4.25	66.44	66.44	81	180.59	180.59	<LOQ	<LOQ
7.3	38.81	38.81	31	19.33	19.33	<LOQ	<LOQ
4.25	45.39	45.39	48	22.19	22.19	<LOQ	<LOQ
7.3	9.86	9.86	34	10.51	10.51	<LOQ	<LOQ
4.25	46.2	46.2	61	48.44	48.44	<LOQ	<LOQ
7.3	38.07	38.07	27	16.19	16.19	<LOQ	<LOQ
7.3	75.16	75.16	25	72.79	72.79	<LOQ	<LOQ
4.25	162.35	162.35	35	763.68	763.68	<LOQ	<LOQ
7.3	38.7	38.7	47	34.52	34.52	<LOQ	<LOQ
4.25	117.04	117.04	59	636.88	636.88	<LOQ	<LOQ
4.25	142.52	142.52	60	718.09	718.09	<LOQ	<LOQ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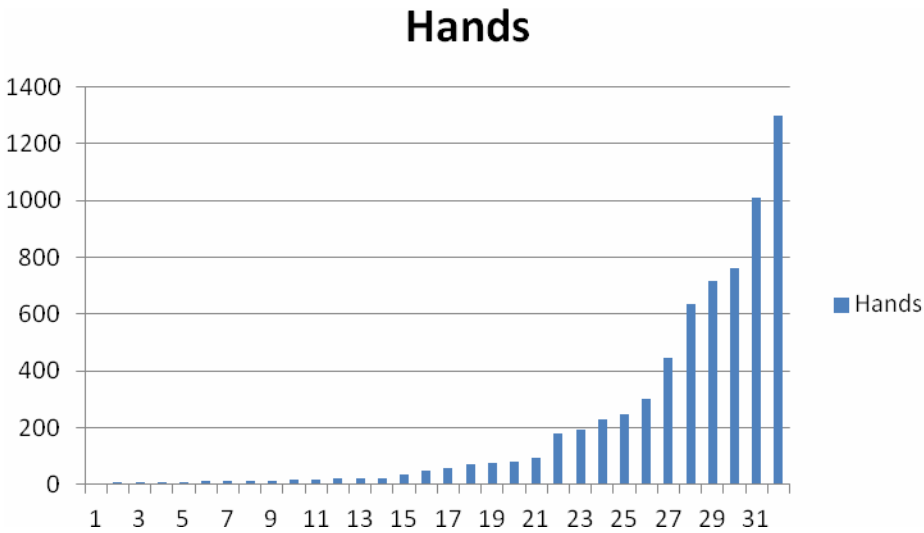
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Hands

Example 2: Dutch pest control spraying (Synthetic pyrethroid)

Low pressure, indoor spraying of water-based pest control products in the Netherlands. Includes the preparation and dilution of the product to a suitable in-use concentration

Amount _appld	Bodyld _lower	Bodyld _upper	duration	Handsld _lower	Handsld _upper	Inhaled _lower	Inhaled _upper
4.5	35434.7	35434.7	115	28234.7	28234.7	5.5	5.5
50	60750.9	60750.9	40	27074.3	27074.3	241.8	241.8
10	1302.6	1302.6	68	611.8	611.8	3.7	3.7
5	585.1	585.1	30	2128.6	2128.6	1.3	1.3
10	3320.8	3320.8	70	1860.2	1860.2	16.3	16.3
7	2968.9	2968.9	81	2705.6	2705.6	15.4	15.4
8	2438.9	2438.9	38	183.3	183.3	5.3	5.3
8	1247.4	1247.4	62	289.5	289.5	2.7	2.7
5	590.5	590.5	90	334.7	334.7	2.2	2.2
15	1155.7	1155.7	125	2787.7	2787.7	9.8	9.8
7	2256.5	2256.5	79	933.6	933.6	24.8	24.8
50	3653.1	3653.1	70	59695.4	59695.4	577.8	577.8
6	3080.1	3080.1	114	25915.8	25915.8	6.9	6.9
6	2839.8	2839.8	62	21466.0	21466.0	4.5	4.5
15	237.2	237.2	90	180.2	180.2	1.5	1.5
15	506.8	506.8	159	1220.7	1220.7	2.5	2.5

2.3 Bystander and Resident exposure

The BREAM model has been developed in the UK by Fera and Silsoe TAG, which provides a distribution for exposure to spray drift (particulate). Exposure to the pesticide vapour and dermal exposure form contact with contaminated surfaces is being added to the model. There are default data for vapour concentrations surrounding treated field from the USA, Germany and UK field studies. The SHEDS model may also provide some useful model data for residential exposure.

Empirical approaches based on spray drift studies which have been developed in the UK with the BREAM model. This model currently uses arable drift data.

An important aspect in estimating bystander and resident exposure is the data on nature and frequency of human activities which potentially lead to exposure. However, there is a significant lack of information on such behaviours, this might be overcome by using data from BROWSE.

Resident exposure includes exposures which can occur for the bystander, but has the added exposure which occurs at home and in the garden.

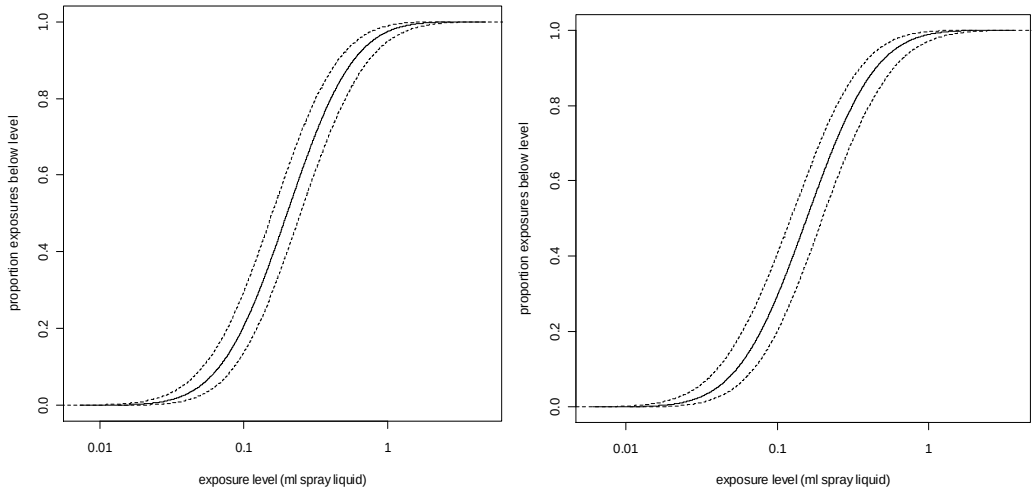
Empirical approaches are based on monitoring of airborne residues both particulate and volatile fractions together with and spray drift fallout as for bystander exposure developed in the UK and added to the BREAM model.

There are still limited data sets on post application volatilisation, although this is improving with Defra funded studies in the UK. As with other exposure scenarios there are limited data for the frequency of human activities leading to exposure.

Below there are some examples of data from the BREAM model. There are various input parameters which can be used. For this example the following have been chosen as typical inputs, which gives 8 scenarios.

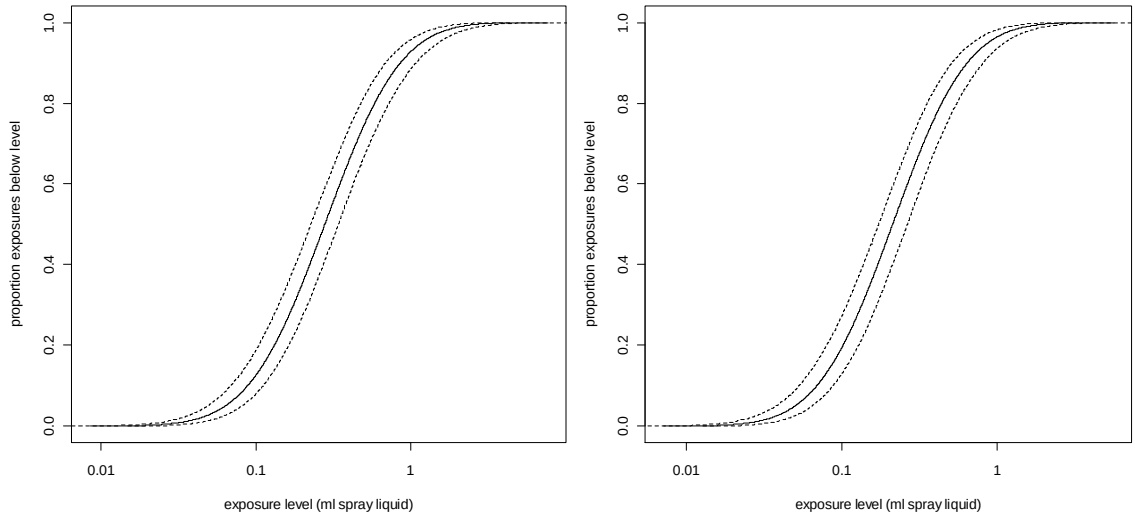
Forward speed	8 kph	12 kph
Wind speed	2 m/s	4 m/s
Boom height	0.5 m	0.7 m

Nozzle type is assumed to be same in each case, the reference F110 03



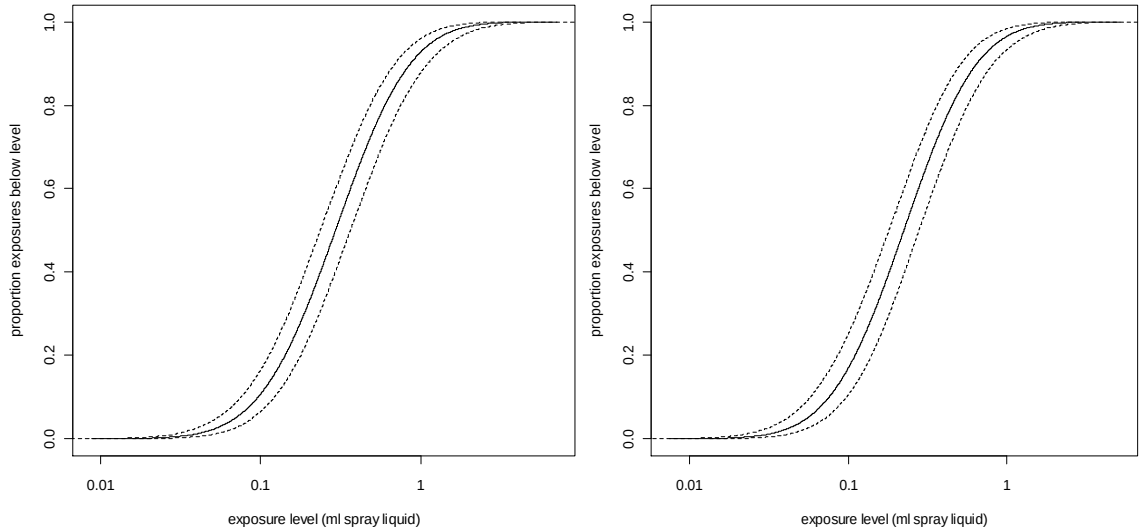
Forward Speed = 8 km/h, Boom Height = 0.5 m, Wind Speed = 2 m/s,
Adult, Child Bystander 2m downwind of sprayer with 48 nozzles. Pointwise 95% CI included for quantiles

		Mean	75th percentile	95th percentile
Adult	Dermal (external)	0.28	0.35	0.79
	Dermal (internal)	0.028	0.035	0.079
Child	Dermal (external)	0.22	0.27	0.61
	Dermal (internal)	0.022	0.027	0.061



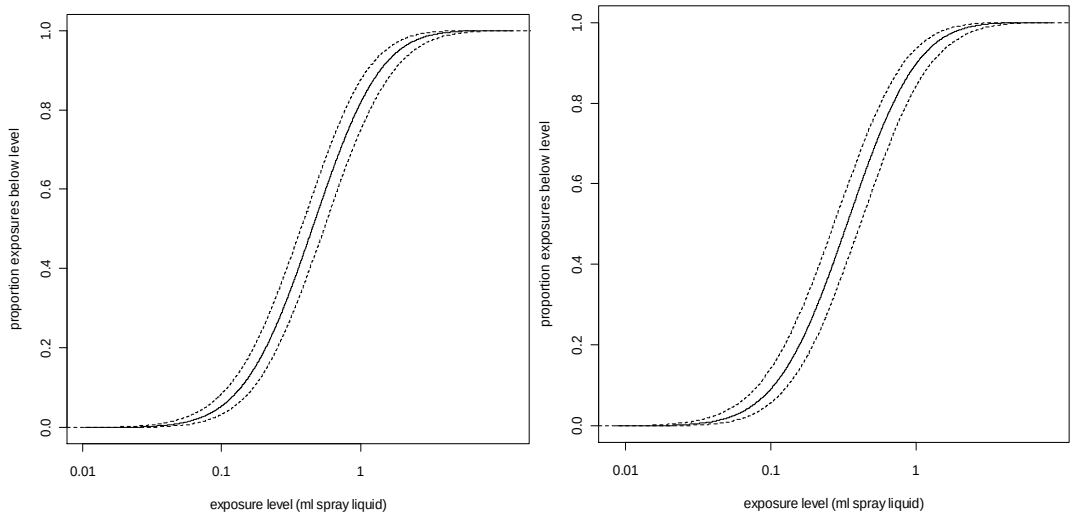
Forward Speed = 8 km/h, Boom Height = 0.5 m, Wind Speed = 4 m/s,
Adult, Child Bystander 2m downwind of sprayer with 48 nozzles. Pointwise 95% CI included for quantiles

		Mean	75th percentile	95th percentile
Adult	Dermal (external)	0.41	0.51	1.18
	Dermal (internal)	0.041	0.051	0.118
Child	Dermal (external)	0.31	0.38	0.88
	Dermal (internal)	0.031	0.038	0.088



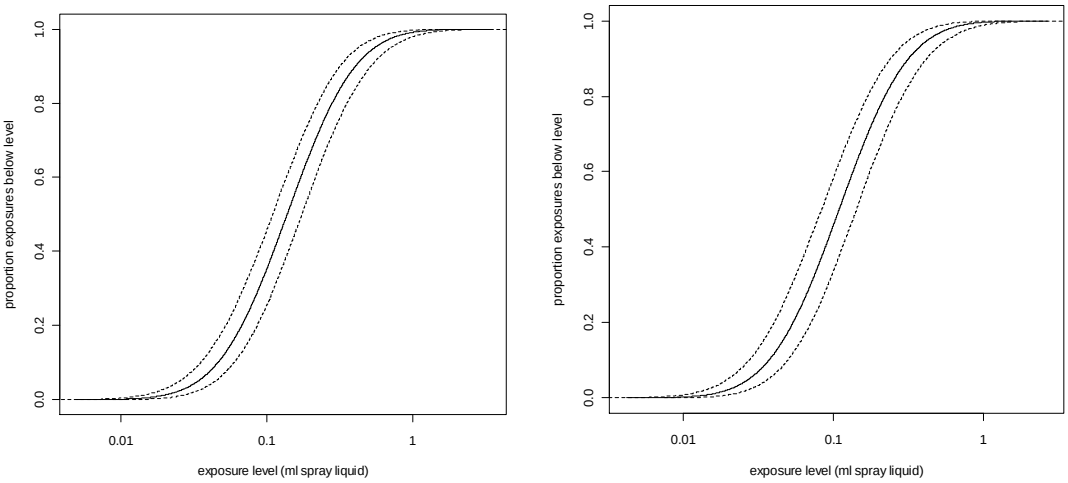
Forward Speed = 8 km/h, Boom Height = 0.7 m, Wind Speed = 2 m/s,
Adult, Child Bystander 2m downwind of sprayer with 48 nozzles. Pointwise 95% CI included for quantiles

		Mean	75th percentile	95th percentile
Adult	Dermal (external)	0.42	0.52	1.18
	Dermal (internal)	0.042	0.052	0.118
Child	Dermal (external)	0.32	0.39	0.88
	Dermal (internal)	0.032	0.039	0.088



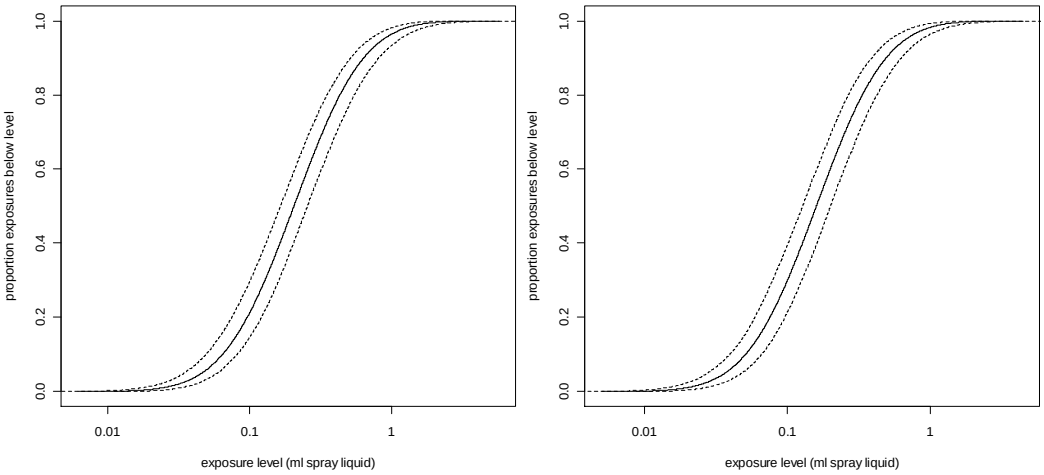
Forward Speed = 8 km/h, Boom Height = 0.7 m, Wind Speed = 4 m/s,
Adult, Child Bystander 2m downwind of sprayer with 48 nozzles. Pointwise 95% CI included for quantiles

		Mean	75th percentile	95th percentile
Adult	Dermal (external)	0.66	0.82	1.92
	Dermal (internal)	0.066	0.082	0.192
Child	Dermal (external)	0.49	0.61	1.40
	Dermal (internal)	0.049	0.061	0.140



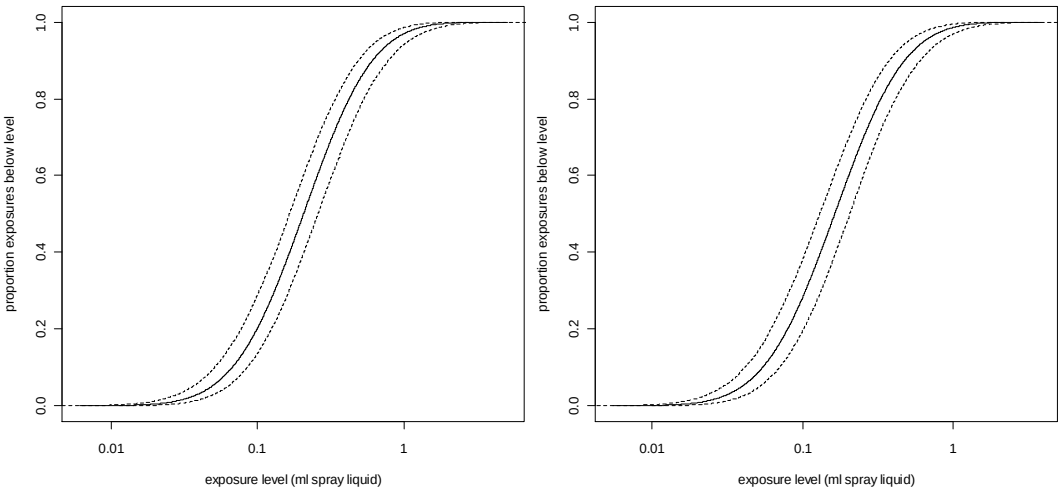
Forward Speed = 12 km/h, Boom Height = 0.5 m, Wind Speed = 2 m/s,
Adult, Child Bystander 2m downwind of sprayer with 48 nozzles. Pointwise 95% CI included for quantiles

		Mean	75th percentile	95th percentile
Adult	Dermal (external)	0.20	0.24	0.55
	Dermal (internal)	0.020	0.024	0.055
Child	Dermal (external)	0.15	0.19	0.43
	Dermal (internal)	0.015	0.019	0.043



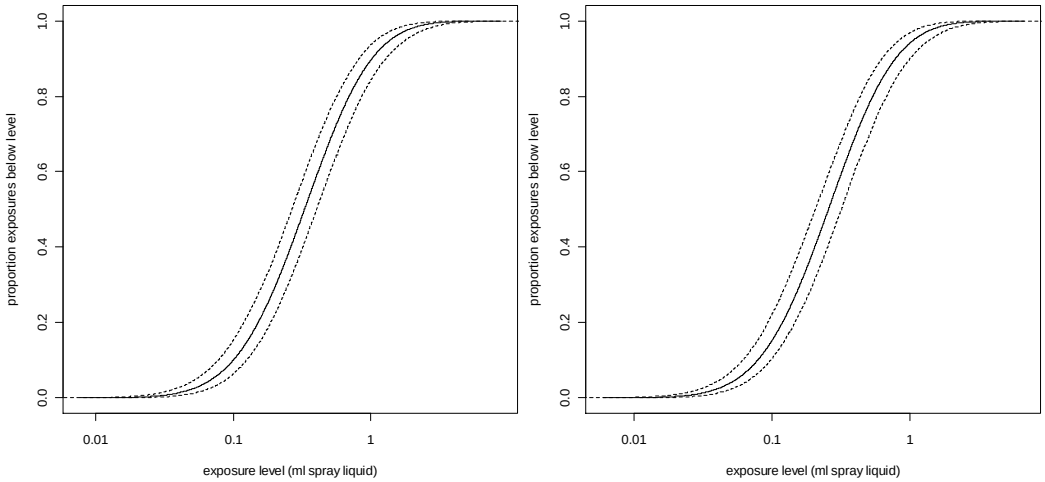
Forward Speed = 12 km/h, Boom Height = 0.5 m, Wind Speed = 4 m/s,
Adult, Child Bystander 2m downwind of sprayer with 48 nozzles. Pointwise 95% CI included for quantiles

		Mean	75th percentile	95th percentile
Adult	Dermal (external)	0.30	0.38	0.88
	Dermal (internal)	0.030	0.038	0.088
Child	Dermal (external)	0.23	0.29	0.68
	Dermal (internal)	0.023	0.029	0.068



Forward Speed = 12 km/h, Boom Height = 0.7 m, Wind Speed = 2 m/s,
Adult, Child Bystander 2m downwind of sprayer with 48 nozzles. Pointwise 95% CI included for quantiles

		Mean	75th percentile	95th percentile
Adult	Dermal (external)	0.30	0.37	0.84
	Dermal (internal)	0.030	0.037	0.084
Child	Dermal (external)	0.23	0.29	0.65
	Dermal (internal)	0.023	0.029	0.065



Forward Speed = 12 km/h, Boom Height = 0.7 m, Wind Speed = 4 m/s,
Adult, Child Bystander 2m downwind of sprayer with 48 nozzles. Pointwise 95% CI included for quantiles

		Mean	75th percentile	95th percentile
Adult	Dermal (external)	0.48	0.60	1.40
	Dermal (internal)	0.048	0.060	0.140
Child	Dermal (external)	0.37	0.47	1.07
	Dermal (internal)	0.037	0.047	0.107

2.4 Worker exposure

Data on worker exposures are much less common than for operator exposure to pesticides. There are some limited data published for re-entry tasks in some crops which are currently used for regulatory purposes in the EU. This is summarised in the EUROPOEM empirical model giving point estimates, basing exposure on relationship to work task activity, which determines the Transfer Coefficient (TC) or contact with the crop.

The dislodgeable foliar residue (DFR) data is used to estimate the amount of pesticide transferred to the worker based on the TC over a specific period of time. As with operator exposure data on actual working patterns, and task durations are not available. Such information will become available from the BROWSE and EFSA project during 2011 and 2012.

By evaluating the data as it becomes available then decisions can be made as to whether there is a need to consider separately

- PPP
- Biocides
- Veterinary medicines

2.5 Home and garden (amateur) use, consumer products etc.

The UK POEM can be used for some of the typical uses encountered for this type of pesticide application. Defra funded studies have generated PDE for amateur users in the UK. A French trade association also generated some representative data for similar users in France.

There are limited data on exposure, nature and frequency of human activities leading to exposure through the use of amateur pesticides, although some data are known to be being generated as part of the EFSA project CT/EFSA/PPR/2010/05.

ACROPOLIS will use such data as it becomes available during 2012 together with information form the fact sheets supporting ConsExpo

ConsExpo

The generic model ConsExpo (Bremmer *et al.)* a computer model developed by the RIVM, consists of general mathematical models allowing estimations to be made for the exposure to substances from non-food consumer products. Little is known about the use patterns and exposures, so only limited data have been used in the model.

The ConsExpo calculations and estimations give a realistic worst-case scenario, and consider consumers who may be frequent users of a product, but where exposure mitigation is also limited. For the estimations in the ConsExpo model, the 99th percentile of exposure and uptake is calculated by multiplying 75th percentiles parameter values, which given the number of parameters for each model and the relationship between the parameters it is expected that in general the calculated values for exposure and uptake will result in a 99th percentile. The models themselves are based on mathematical models solely and are not validated with data. The defaults for the models (presented

in the factsheets) are based on empirical data. A quality factor is given for each parameter to show the reliability of the parameter value presented.

There are a large number of product types, and information for each group of products is described in a fact sheet. Paint, cosmetics, children's toys and cleaning products are examples fact sheets which have been published already. This fact sheet covers the use of pest control products by consumers. In the factsheet eight product categories are described, including sprays, dusting powders, repellents, electrical evaporators and baits. To assess exposure of compounds in the pest control products default values for each product category have been determined.

1. Sprays
    a. Targeted spot-application
    b. Crack and crevice application
    c. General surface application
    d. Air space application
2. Evaporation from strips and cassettes
3. Electric evaporation
4. Insect repellents
5. Baits
6. Dusting powders
7. Textile biocides, gasses and foggers

ConsExpo v5 (beta-release January 2011) facilitates the exposure assessment for different populations, to multiple products, in various exposure scenarios, combining all routes and pathways of exposure into a total, aggregate exposure estimate for a population. In this new version the methods for probabilistic exposure evaluation have been improved. In addition to existing parametric probability density functions, also beta distributions are implemented in the software.

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APPENEDIX I: Review of existing models

Introduction

A comprehensive review has been done to indentify operator exposure models that are currently used or are under development. From these models the scenarios being covered, the underlying assumptions and databases, critical default values used and the level of protection in the exposure estimates were investigated.

In principle, two main types of models can be distinguished: descriptive and predictive models. Predictive models are based on scientific causality and described by a numerical construct. Depending on the quality (and detail) of the model, the reality is reflected to a varying degree. Descriptive models are mostly based on empirical knowledge and data sets.

Models being considered in ACROPOLIS include the following

PPP models

- UK POEM (UK model)
- BBA model (German model)
- Dutch model, including Dutch greenhouse model
- EUROPOEM I/EUROPOEM II
- PHED
- SEEDTropex
- Southern European greenhouse model
- ConsExpo

Other models (industrial chemicals and biocides)

- Conceptual model dermal exposure (Schneider et al., 1999)
- RiskOfDerm model and toolkit (dermal)
- DREAM (dermal)
- BEAT (dermal & inhalation)
- TNsG Human Exposure Biocides (dermal & inhalation)
- ConsExpo (dermal & inhalation, models)
- EASE (dermal & inhalation)
- ECETOC-TRA (dermal & inhalation)
- Stoffenmanager (inhalation & dermal qualitatively)
- ART (inhalation)

Other models being considered as possible tools for ACROPOLIS

- **Calendex™ –** Complex model for performing aggregate and cumulative assessments of population exposures to pesticides. The fact that the model contains hard-wired US data sets and its focus on pesticides limits its utility for comprehensive exposure assessment.
- **CalTOX –** Model of intermediate complexity, which simulates both chemical fate in the environment and subsequent human exposure via a comprehensive range of pathways. Designed for local hazardous waste site exposures but may be more generally applicable.
- **CARES –** Population-based model for performing aggregate and cumulative assessments of pesticide exposures. Focuses on a limited range of exposure situations and uses US datasets but model is freely available and has the potential to be adapted for additional scenarios.
- **CLEA –** UK developed model for assessing exposures levels resulting from direct and indirect contact with contaminated soil and for defining soil guideline values. Limited consideration of exposure situations and pathways and conservative nature restrict its utility as a comprehensive exposure assessment tool.
- **Consumer -** Simple model for assessing dietary pesticide exposures using UK consumption data. Only considers a single exposure pathway and adopts a conservative approach.
- **EUSES –** Comprehensive model system, which assesses chemical fate and human exposure via the environment, diet, consumer products and the workplace. Designed for a specific legislative purpose and lacks flexibility.
- **Intake Programme –** Simple dietary exposure assessment tool. Lacks sophistication of US dietary models in terms of how uncertainty and variability are incorporated into model calculations. Only considers a single exposure pathway.
- **LifeLine™ –** Complex model for simulating aggregate and cumulative pesticide exposure levels for US populations. Incorporates variability and uncertainty in a sophisticated manner. Applicability of model for non-pesticides is currently limited.
- **REx** – Flexible system for assessing residential exposure levels. Scenarios are designed for pesticide products thus restricting the general remit of the model.
- **RISC** – Mechanistic model of chemical fate and subsequent human exposures relating to contaminated land, air and water. Both screening level and higher tier assessments can be performed using the model. Applicable for a limited range of exposure situations.
- **SHEDS** – Series of models in development for assessing US population exposures to a variety of contaminants (current versions for pesticides and particulate matter). Incorporates detailed activity data currently unavailable for the UK.

Existing models for industrial chemicals

- Advanced REACH Tool (ART)
- DeRmal Exposure Assessment Method (DREAM)
- ECETOC-TRA
- RISKOFDERM model
- Stoffenmanager

Other models and/or tools

- Chemical Screening Tool For Exposures & Environmental Releases (ChemSTEER)
- Control of Substances Hazardous to Health (COSHH) Essentials
- European Union System for the Evaluation of Substances (EUSES)
- Exposure and Fate Assessment Screening Tool (E-FAST)
- Metals EASE (MEASE)
- Probabilistic Methodology for Improving Solvent Exposure Assessment (PROMISE©)