Recommendation no. 3

of the BPC Ad hoc Working Group on Human Exposure

Spraying models for assessing exposure to insecticides for low pressure downward uses

(Agreed at the Human Health Working Group IV on 17 September 2014)

1. Background

A. Background information

During a Technical Meeting discussion of a PT18 active substance dossier, a point was raised about which model should be used to refine exposure of professional application by low pressure spraying (knapsack or hand held) for downward uses.

Briefly, UK-POEM was not considered well designed for indoor applications and other models for spray application were available in the TNsG which should be used for this kind of exposure assessment. The TNsG 2002 should be used at the first tier and the use of the BEAT model was acceptable to make a refinement.

The question as to whether it is possible to refine the spraying model 1 of the TNsG 2002 with BEAT spraying models in the context of professional exposure to insecticides was put forward to the former HEEG (Human Exposure Expert Group). Based on the work started by HEEG, the present recommendation was prepared by the Ad hoc Working Group on Human Exposure.

B. Spraying model 1 from TNsG 2002

Spraying model 1 is the classical model used for professional low pressure spray applications in PT 18 substances or products applications.

This model is described in the TNsG 2002 part 2 as follows:

User	Professionals, principally
Task	Mixing and loading liquids and powders in compression sprayers or dusting applicators, and applying at 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards. Scenario: low-pressure insecticide application
Data source	HSE surveys 1992-3, IOM study on PPE, 1996
Reference	EH74/3

The *User guidance on human exposure to biocidal product* (2002) recommends the following exposure values: inhalation 104 mg b.p.[1]/m^3 (50^{th} percentile), potential body (75^{th} percentile) 92 mg b.p./min, potential hands (highest value) 181 mg b.p./min, actual hands (75^{th} percentile) 10.7 mg b.p./min.

This model covers a wide range of situation liquids/powders, indoor/outdoor, overhead and downwards. These situations can lead to different levels of exposure particularly in the case of overhead application versus downward application. If the application is only downward, it will be an overestimate of the exposure. This is the case for product application where there is no overhead use. Moreover, no details are available on the repartition of the measurements between the different categories: liquids/powders, indoor/outdoor, overhead and downwards.

[1] b.p.: all exposure values in this paper are expressed in mg in-use biocidal product.

2. Aim of the recommendation

The aim of this recommendation is to compare the spraying model 1 of the TNsG 2002 with other available models in order to identify the most suitable approach for assessing exposure to insecticides for low pressure downward uses.

3. Discussion

Considering that UK-POEM is not representative of indoor biocides applications, the discussion is focused on the following models: BEAT, ART (inhalation exposure only) and RISKOFDERM (dermal exposure only).

The studies with spraying applications for insecticide applications or close to insecticide applications from BEAT, RISKOFDERM and ART are listed below (more details are available in Annex 1):

1. BEAT / RISKOFDERM - Public hygiene insecticide - Llewellyn, D.M., Brazier, A., Cocker, J., Evans, J., Hampton, J., Nutley, B.P., White, J., (1996). Occupational exposure to permethrin during its use as a public hygiene insecticide. Annals of Occupational Hygiene (40) 499-509
2. BEAT / RISKOFDERM - Herbicide spraying (CDA) - Johnson P.D., Rimmer D.A., Garrod A.N.I., Helps J.E., Mawdsley C. (2005) Operator exposure when applying Amenity Herbicides by All-Terrain Vehicles and Controlled Droplet Applicators. Annals of Occupational Hygiene (49) 25-32
3. BEAT / ART*[2] / RISKOFDERM* - Dutch pest control spraying – no references[3]
4. BEAT / RISKOFDERM - Remedial biocides - Garrod A.N.I., Rimmer, D.A., Robershaw, L., Jones, T., (1998). Occupational exposure through spraying remedial pesticides. Annals of Occupational Hygiene (42) 159-165
5. ART / RISKOFDERM / BEAT* - Spraying biocide by pest control operators; Pest control, de Cock and van Drooge (2002). Field study on occupational exposure during spraying of biocidal products by pest control operators using deltamethrin and (b)-cyfluthrin. TNO-report V3806. TNO, Zeist, The Netherlands[4]
6. ART - Spraying of biocide by pest control operators using hand-held pumps; Proj ref: V4534
7. ART - Spraying pesticides in greenhouses using spray pistols; Proj ref: V94.300

BEAT, ART and RISKOFDERM are based on almost the same studies. Considering the year of publication, it is highly probable that the study from LLewellyn (1996) is part of the spraying model 1. The *Herbicide spraying* (CDA) study from Johnson is the one of the fogging and misting model 1 from TNsG 2002. The remedial biocide study from Garrod (1998) is the same as the spraying model 2 from the TNsG 2002 and is designed for medium pressure application (4-7 bar with lance). RISKOFDERM and ART take into account in their spray model others studies covering: paint spraying, powder spraying disinfection, PPP spraying and with other kind of spray equipment, such as spray lance, spray boom,

[2] The asterisk ("*") indicates that a model may be covered by the study cited.
[3] This study seems to be the same as the study 5 (Cock and van Drooge, 2002), including ART and RISKOFDERM.
[4] This study seems to be the same as the study 3 (BEAT-Dutch pest control spraying).

mounted tractors. In the presented studies, except for the *Herbicide spraying* (CDA) (Johnson, 2005), data in the BEAT database is not separated between overhead and downwards data.

The CDA study is based on a specific spraying device composed of a lance with lightweight spinning discs, fed with pesticide from a knapsack container for downward application. This kind of device is very specific and should not be compared to classical spray application. So this study will not be taken into account in the analysis.

For the other studies, merging overhead and downwards data can explain the wide range of exposure, for example for the model BEAT - *Public hygiene insecticide*: body 0-427 mg b.p./min[5]; hand in gloves 0-53.1 mg b.p./min; inhalation 0-628 mg b.p./m^3.

Therefore, there is a need to take into account the factor of the direction of the spray. However, without the raw datasets of the publications, it is difficult to set exposure values for downward application.

Moreover, in BEAT there are some discrepancies for exposure values among the database, the proposed worked examples and the publication. For example the study *Public hygiene insecticide* (Llewellyn, 1996) indicates 45 measurement when BEAT contains up to 64 measurements for body exposure. Some discrepancies are identified also between the proposed scenario and the data base. For inhalation, the database proposes to use the 95th percentile with a value of 259 mg b.p./m^3 and the scenario is based on the 75th percentile with a value of 35 mg b.p./m^3, while in the database the value of the 75th percentile is 0.806 mg b.p./m^3.

In light of this consideration, BEAT seems not to be the most appropriate model for low pressure downward uses.

As the designers of ART and RISKOFDERM had access to the raw data of the studies, an analysis was possible to determine a contributing factor for the direction of spray. Therefore, a combination of these two models could be the appropriate approach.

ART and RISKOFDERM have two important parameters in common which are the application rate and the distance between the worker and the sources. Application rates are pending on efficacy data. ART proposes ranges from very low to high. The ones corresponding to insecticides application are the low range of 0.03-0.3l/min and the medium range 0.3-3 l/min. Concerning RISKOFDERM, the real application has to be set. The second parameter, the distance between workers and the source, should be set at less than one meter (near field) as the equipment is handheld except maybe for specific spray devices with lance of more than one meter long.

Table 1 shows an example of the outputs from ART and RISKOFDERM with medium application rate and near field exposure. Table 2 reports the parameters used for the simulation in RISKOFDERM and ART.

[5] In BEAT model, exposures are expressed in µl b.p./min or µl b.p./m^3. As the majority of insecticides products for spray application are diluted in water, it has been considered a density of 1 mg/µl.

Table 1: Example of outputs from ART and RISKOFDERM with medium application rate and near field exposure*

Percentile	Inhalation from ART (mg b.p./m^3)	Potential body from RISKOFDERM (mg b.p./min)**		Potential hand exposure from RISKOFDERM (mg b.p./min)	
	Application rate: 0.3-3 l/min	Application rate: 0.35 l/min	Application rate: 3 l/min	Application rate: 0.35 l/min	Application rate: 3 l/min
50th	6.8	26.7	106	7.66	16.8
75th	12	89.4	354	25.6	56.2
95th	33	509	The value is out of range of the model.	146	The value is out of range of the model.

* The indicative values from spraying model 1 are given for comparison: inhalation 104 mg b.p./m^3 (50th percentile), potential body (75th percentile) 92 mg b.p./min, potential hands (highest value) 181 mg b.p./min

** In RISKOFDERM model, exposures are expressed in µl/min. As the majority of insecticides products for spray application are diluted in water, it has been considered a density of 1 mg/µl.

Table 2: Parameters used for the simulation

RISKOFDERM simulation 2	ART simulation 2
Model configuration: - indoor application - spraying downward - airflow not clearly away from the worker - no segregation of the worker from the source - source at less than 1 meter from the worker - liquid non volatile - application rate 0.35l/min (from applicant) and application rate 3 l/min	Model configuration: - indoor application - spraying downward - no segregation of the worker from the source - source at less than 1 meter from the worker (near field) - liquid non volatile - application rate 0.3-3l/min - natural good ventilation - vapour pressure <10 Pa*

* 10 Pa is a trigger value in ART. Below 10 Pa, workers are considered to be exposed to the aerosol generated during activities. Above 10 Pa, workers are considered to be exposed to volatile substance.

More details are available in the Annexes.

For inhalation exposure, ART gives exposure values (33 mg b.p./m^3 for 95th percentile) below spraying model 1 (104 mg b.p./m^3 for 50th percentile). This reflects well the diminution of aerosol in the breathing zone of the worker.

For potential body exposure, RISKOFDERM with an application rate of 0.35 l/min gives results really close to the spraying model 1 respectively for the 75th percentile 89.4 mg

b.p./min against 92 mg b.p./min. However, it should be noted that the increase in the application rate to up to 3 l/min gives more than 3.5-fold exposure values compared to the spraying model 1. As a consequence, this parameter is really sensible and an accurate value for the use is needed. This should be representative of a high contamination of legs for downward spraying.

With regard to potential hand exposure, the application rate is still sensible, but the results from RISKOFDERM (56.2 mg b.p./min for 75th percentile) are still below the values from the spraying model 1 (181 mg b.p./min max value).

The 75th percentile from RISKOFDERM seems to be reasonable for exposure estimates and in line with values from the spraying model 1.

Concerning ART, TNO recommends using the upper bound of the interquartile of the 75th percentile.

4. Proposal for harmonisation

Considering that BEAT seems not to be the most appropriate model for low pressure downward uses and that the Spraying model 1 may underestimate dermal exposure for the application rate of 3 l/min, it is proposed to use a combination of ART and RISKOFDERM to assess inhalation and dermal exposure, respectively.

The validity range of RISKOFDERM is shown in Figure 1. The validity range of ART is not presented, as it is based on closely similar studies and the validity range should be close to RISKOFDERM. ART simulations used for the determination of default values cover substances with vapour pressure < 10 Pa.

Figure 1: validity range of RISKOFDERM

Validity ranges of the model

The model is valid for the situations fitting with the situations covered in the underlying data sets. Outside of these situations the validity is not sure.
In the next table the boundaries of the measured data for use rate and duration are presented per process.

Process	Use rate (L/min or kg/min) Solids	Liquids	Duration (minutes) Solids	Liquids	Remarks
Filling, mixing and loading	0,56 - 225	0,008 - 257	1 - 20	0,33 - 125	
Wiping	---	0,0017 - 1,18	---	5 - 35	There is also a boundary to the combination of use rate and duration
Dispersion hand-held tools	---	0,0001 - 1,1	---	1 - 445	There is also a boundary to the combination of use rate and duration
Spraying	0,02 - 0,12	0,04 - 50,4	4 - 90	3 - 600	Combination of high use rate and high duration was very rare
Immersion	---	---	---	4 - 483	
Mechanical treatment	---	---	18 - 154	47 - 214	

Concerning both models, a near field exposure has to be considered with an appropriate application rate. For spraying pressure of 1-3 bar, data from industry allowed us to confirm that an application rate of 0.3 to 3 l/min is a reasonable worst case. For pressure of 4-7 bar, this approach is not applicable since the application rate is higher (e.g. use of spraying model 2).

If the application rate is unknown and for substances with a vapour pressure <10 Pa, the default inhalation exposure value for professional low pressure downward spraying is proposed as follows:

Percentile	Inhalation from ART (mg b.p./m^3)
	Application rate: 0.3-3 l/min
75th	12

The default dermal exposure values for professional low pressure downward spraying will be developed in due course based on exposure data provided by Industry.

If the application rate is available, RISKOFDERM can be used with the following parameters:

RISKOFDERM simulation
Model configuration: - indoor application - spraying downward - airflow not clearly away from the worker - no segregation of the worker from the source - source at less than 1 meter from the worker - liquid non volatile - application rate: pending on data provided by applicant in the range of RISKOFDERM validity (min 0.04l/min; max 50.4 l/min) - percentile 75th

5. References

- de Cock and van Drooge (2002) Field study on occupational exposure during spraying of biocidal products by pest control operators using deltamethrin and (b)-cyfluthrin. TNO-report V3806. TNO, Zeist, The Netherlands
- Garrod A.N.I., Rimmer D.A., Robershaw L., Jones T., (1998). Occupational exposure through spraying remedial pesticides. Annals of Occupational Hygiene (42) 159-165
- Johnson P.D., Rimmer D.A., Garrod A.N.I., Helps J.E., Mawdsley C. (2005) Operator exposure when applying Amenity Herbicides by All-Terrain Vehicles and Controlled Droplet Applicators. Annals of Occupational Hygiene (49) 25-32
- Llewellyn D.M., Brazier A., Cocker J., Evans J., Hampton J., Nutley B.P., White J., (1996). Occupational exposure to permethrin during its use as a public hygiene insecticide. Annals of Occupational Hygiene (40) 499-509
- RISKOFDERM Dermal model: Warren N.D., Marquart H, Christopher Y., Laitinen J., Van Hemmen J.J. 2006. Task-based dermal exposure models for regulatory risk assessment, Ann. Occup. Hyg. 50, 491-503
- Spraying of biocide by pest control operators using hand-held pumps; Proj ref: V4534, ART project
- Spraying pesticides in greenhouses using spray pistols; Proj ref: V94.300, ART project
- Technical Notes for Guidance on human Exposure to biocidal products, 2002; http://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg+human+exposure+2002_en.pdf
- Technical Notes for Guidance human exposure to biocidal products, 2007; http://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg-human-exposure-2007_en.pdf

6. Annexes

6.1 Annex 1: Studies with spraying applications PT18

The Annex is available under "Recommendations of the Ad hoc Working Group on Human Exposure": http://echa.europa.eu/web/guest/view-article/-/journal_content/title/recommendations-of-the-ad-hoc-working-group-on-human-exposure

6.2 Annex 2: ART spray, far field, full shift

Details for Activity spraying

Emission sources: Near field

Far field ✓

Duration (mins): 480

Far-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	9.9 Pa
Liquid weight fraction	1
Viscosity	Low
Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Moderate application rate (0.3 - 3 l/minute)
Spray direction	Only downward
Spray technique	Spraying with no or low compressed air use
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	1000 m³

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Segregation	No segregation (0.00 % reduction)
Personal enclosure	No personal enclosure (0.00 % reduction)
Dispersion	
Ventilation rate	Only good natural ventilation

Predicted exposure levels
ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results
The predicted 75th percentile full-shift exposure is 0.71 mg/m³.
The inter-quartile confidence interval is 0.34 mg/m³ to 1.5 mg/m³.

6.3 Annex 3: ART spray, far field, long term

Details for Activity spraying

Emission sources: Near field

Far field ✓

Duration (mins): 480

Far-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	9.9 Pa
Liquid weight fraction	1
Viscosity	Low
Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Moderate application rate (0.3 - 3 l/minute)
Spray direction	Only downward
Spray technique	Spraying with no or low compressed air use
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	1000 m³

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Segregation	No segregation (0.00 % reduction)
Personal enclosure	No personal enclosure (0.00 % reduction)
Dispersion	
Ventilation rate	Only good natural ventilation

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 75th percentile long-term exposure is 0.78 mg/m³.

The inter-quartile confidence interval is 0.36 mg/m³ to 1.7 mg/m³.

6.4 Annex 4: ART spray, near field, full shift

Details for Activity spraying

Emission sources: Near field ✓
Far field

Duration (mins): 480

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	9.99 Pa
Liquid weight fraction	1
Viscosity	Low

Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Moderate application rate (0.3 - 3 l/minute)
Spray direction	Only downward
Spray technique	Spraying with no or low compressed air use

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	1000 m³

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Dispersion	
Ventilation rate	Only good natural ventilation

Predicted exposure levels
ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results
The predicted 75th percentile full-shift exposure is 5 mg/m^3.
The inter-quartile confidence interval is 2.3 mg/m^3 to 11 mg/m^3.

6.5 Annex 5: ART spray, near field, long term

Details for Activity spraying

Emission sources: Near field ✓ Duration (mins): 480

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	9.99 Pa
Liquid weight fraction	1
Viscosity	Low
Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Moderate application rate (0.3 - 3 l/minute)
Spray direction	Only downward
Spray technique	Spraying with no or low compressed air use
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	1000 m³

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	Only good natural ventilation

Predicted exposure levels
ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results
The predicted 75th percentile long-term exposure is 5.3 mg/m^3.
The inter-quartile confidence interval is 2.4 mg/m^3 to 12 mg/m^3.

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