EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Toxicology and Chemical Substances Unit

HEEG Opinion 1

Ispra, 06/04/2008

HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale

Agreed at TM I08

1) Background

Following a proposal for the amendment of the Mixing and loading Model 7 in the TNsG on human exposure, it was agreed at the Technical meeting (TMV07, item TOX5f) to check for alternative models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale. This scenario is present in many dossiers in the 3rd priority list and it is necessary that the assessors can use reliable and relevant data for exposure assessment

The Human Exposure Expert Group prepared this document which was brought up for discussion at the TMI08 and agreed upon.

2) Opinion of the HEEG

a) No perfect model exists; there can be appreciable variation between the indicative values. This is partly due to the variation between the conditions of application and the variability in the models. Consequently, it is difficult to choose the best model for each application, making the Bayesian option (BEAT) the best approach.

b) As a general rule, the models in the TNsG version 2 (and BEAT and to some extent additionally in the text) should be considered in priority. If no specific model can be found, the RISKOFDERM Dermal Model can be used.The evaluators have some tools to calculate the exposure during the scenario under consideration, and will have to take into account the characteristics (product, quantity, equipment, etc.) for choosing and using the most relevant model in each case, when the Bayesian option is not used or not available. The objective of this document is to help the assessor in the choice to make in the latter case.

In the following paper only database models are considered. Other data can also be used. However, the data presented in the first version of the TNsG have been reconsidered for the User Guidance and the second version of the TNsG. When they are not mentioned anymore, the confidence in those models is not very large.

The Bayesian approach has the great advantage that the information of all relevant models in the database are considered, which makes the Bayesian prediction the first choice.

An alternative approach, when no model in the TNsG version 2 is found relevant with the scenario, is to list all relevant models and choose the best one which compares as good as

Joint Research Centre · I-21020 Ispra (VA), Italy · TP 582
Telephone: direct line (+39)0332/78, · Telefax: (+39)0332/789963
E-mail:
http://ihcp.jrc.ec.europa.eu

possible with the scenario that is considered. The confidence in the prediction by the model used depends mainly on three elements:

1. The comparability of the scenario of the model and the one under consideration
2. The robustness of the model dataset in terms of sample size
3. The width of the distribution, which is a measure of the consistency of the dataset

For most models, when a Bayesian approach is not used, only the second and third element are considered in most database models in the computerised database.

The following tables summarise data from:

- Models in BEAT (the computerised database linked to TNsG on human exposure version 2) and the text of TNsG on human exposure version 2
- Models in TNsG on human exposure version 1 and its User Guidance
- EASE (model implemented in EUSES)
- RISKOFDERM Toolkit (semi-quantative model for the dermal exposure assessment and the risk management)
- RISKOFDERM Dermal Model (Excel file which is the recommended model in the REACH guidance)
- The RISKOFDERM Dermal Model used in the following tables is based on the


Riskofderm Mix/Load

attached spreadsheet:

which were thought relevant for the following applications:

1. **solid (powder) loading/dumping**
2. **liquid manual loading/pouring**
3. **liquid (semi-) automated transfer/pumping.**

The models also include some remarks on the reliability, the relevance of these data and recommendations on their use.

1. Solid (powder) loading/dumping				
Source	**Conditions**	**Indicative values : dermal**	**Indicative values : inhalation**	**Remarks Relevancy/Reliability**
TNsG user guidance page 24 *Mixing and loading model 5* TNsG part 2, p 137	Powder	Hands: 10.2 mg/kg a.s. *255 mg/25kg-bag*	0.66 mg/kg a.s. *16 mg/25kg-bag*	Relevant for "relatively large amount". No ventilation.
Dust and soil adhesion model 3 *TNsG part 2, p 181 (Sub model)*	Powder (<30µm) 25 kg-cardboard bags	Hands : 224 mg/min (75th %)		With local exhaust ventilation. Duration: 1-15 min (up to 25 bags)
EASE Intermittent incorporation onto matrix (dry manipulation) Direct handling with or without ventilation	Powder	0.1-1 mg/cm^2/day; *Hands : 0.84 g/day* *Body* : 10 g/day*	Inhalation : without LEV : 5-50 mg/m^3 *(1 mg/min)* with LEV : 2-5 mg/m^3 *(0.1 mg/min)*	EASE is not relevant to estimate dermal exposure. To be avoided.
RISKOFDERM Toolkit *Loading powder*	Powder	Hands : 22 mg/cm^2/h *308mg/min* Body: 0.5mg/cm^2/h * *83mg/min*		Semi-quantitative model, to be avoided.
RISKOFDERM Dermal model *Loading powder*	Powder (more or less dusty)	Hands : 117-897 mg/min Body: 418 mg/min (95%ile)		Range depending on dustability. Influence of other parameters (e.g. ventilation, use rate) can also be evaluated.
Mixing & loading model 7; TNsG part 2 p.142 (corrected)	Powder	*Total without gloves :* *305 mg/min* Under clothes and gloves : 3.05 mg/min	Inhalation: 7.2 mg/m^3 *(0.15 mg/min)*	Potential exposure calculated using a factor 100. Not mentioned in TNsG version 2. To be used carefully.
BEAT : *Loading zinc oxide*	Powder Paper bags	Hands : 18.4 mg/min Body : 125 mg/min		With local exhaust ventilation.

Figures in italic are recalculated

*: considering that the front of the body (gross assumption: 1 m^2) is contaminated.

Joint Research Centre · I-21020 Ispra (VA), Italy · TP 582
Telephone: direct line (+39)0332/78, · Telefax: (+39)0332/789963
E-mail:
http://ihcp.jrc.ec.europa.eu

Comments:

- **For simple loading** (e.g. 1 bag per day), the *M&L model 5* is relevant and probably easier to use, as expressed as mg/kg. It gives also indicative values for inhalation.
- **For repeated loading** (several bags per cycle), several models are available (*dust adhesion model 3* and *Mixing & loading model 7* in TNsG, *loading powder* with RISKOFDERM and *loading zinc oxide* in BEAT). Values from BEAT are globally lower and those from RISKOFDERM Dermal model are higher, with maximal difference by factor 10. The differences may be explained by the differences in the conditions of application, e.g. dustability and use rate. Only RISKOFDERM Dermal model takes such parameters into account. *Mixing & loading model 7* provides actual exposure under gloves. The potential exposure is estimated using a factor 100. Perhaps it would be possible to enter the values from *dust adhesion model 3* (report by TNO) and *Mixing & loading model 7* in BEAT to build a global model with *Loading zinc oxide.* For the inhalation, only EASE and *M&L model 7* provide data. They may be used but significant influence from ventilation and particle size should be taken into account by the experts.
- **For smaller quantities** (< 1kg), data from ConsExpo, e.g. *Disinfectant products fact sheet*, provides reliable data on uses and exposure.

Recommended choices:

- **For simple loading** (e.g. 1 bag per day), *M&L model 5 (Professional pouring formulation from a container into a fixed receiving vessel)* in TNsG version 1 part 2 p.137, User guidance p.24 and TNsG version 2 p.66
- **For repeated loading** (several bags per cycle), *Loading zinc oxide* in BEAT (TNsG version 2). Alternatively: *Loading powder* in RISKOFDERM Dermal model if influence of specific parameters (e.g. dustability, ventilation, use rate) can be assumed and evaluated.
- **For smaller quantities** (< 1kg), data from ConsExpo, e.g. *Disinfectant products fact sheet*

2. Liquid manual loading/pouring				
Source	**Conditions**	**Indicative values : dermal**	**Indicative values : inhalation**	**Remarks Relevancy/Reliability**
Mixing and loading model 4 TNsG part 2, p 136 and User guidance p.24	Liquid 10&20 litres	Hands : 0.5 ml/loading *25-50 mg/kg a.s.*		
[1]*EUROPOEM II database* User guidance p.24	Liquid[1] *up to 20 l*	Hands 8.0 mg/kg a.s. Body 1.95 mg/kg a.s.	0.003 mg/kg a.s.	
Mixing and loading model 6 TNsG part 2, p 138	Paint	Hands actual 8.2 mg/min Hands potential 30 mg/min Body 92 mg/min; 71 mg/kg a.s.	1.9 mg/m^3	Specific to antifouling paints. Indicative, for comparison.
EASE *Intermittent incorporation onto matrix* Direct handling with or without ventilation	Liquid	0.1-1 mg/cm^2/day; *Hands : 0.84 g/day* *Body* : 10 g/day*	100 –300 ppm (moderate volatility, no aerosol) Max 140 ppm if ventilated	Highly dependant on volatility, formation of aerosol and ventilation. EASE is not relevant to estimate dermal exposure. To be avoided
RISKOFDERM Toolkit *Loading liquid*	Liquid	Hands : 0.66 mg/cm^2/h *(9.2 mg/min)* Body 0.17mg/cm^2/h * *(28.3 mg/min)*		Semi-quantitative model, to be avoided.
RISKOFDERM Dermal model *Loading liquid*	Liquid	Hands : 3390 mg/min Body : 2.02 mg/min (95%ile)		Depend on product and conditions (use rate is an important parameter).
Mixing & loading model 7; TNSG part 2 p.142 (corrected)	Liquid	*Total without gloves :* *101 mg/min* Under clothes and gloves : 1.01 mg/min	0.94 mg/m^3	Potential exposure calculated using a factor 100. Not mentioned in TNsG version 2. To be used carefully.
BEAT : *Loading DEGBE*	Liquid 5-560 litres (container or drum)	Hands : 4614 mg/min Body : 18 mg/ min		Very wide distribution but even the maximal values are representative to the scenario.

Figures in italic are recalculated

*: considering that the front of the body (gross assumption: 1 m^2) is contaminated.

Comments:

- For simple loading (e.g. 1 container per day), data from *M&L model 4* and *EUROPOEM II* are relevant and probably easier to use, as expressed as mg/kg. The latter gives also indicative values for inhalation.
- For repeated loading (several containers per cycle), indicative values from *Loading DEGBE* model in BEAT, *Mixing & loading model 7* in TNsG and RiskOfDerm are reported. There is a big difference between the values (more than factor 100), which may be explained by differences in operating conditions and very large distribution inside some models. Measurements in *Loading DEGBE* model have a very wide distribution, but even the maximal values are thought representative to the scenario. *Mixing & loading model 7* provides actual exposure under gloves. The potential exposure is estimated using a factor 100. For the inhalation, only EASE and *M&L model 7* provide data. They can be used but significant influence from ventilation and particle size should be taken into account by the experts.
- For smaller quantities (< 1kg), data from ConsExpo, e.g. *Disinfectant products fact sheet*, and *Mixing&Loading model 2* (TNsG part 2 p134 and user guidance p25) provide reliable data on uses and exposure.

Recommended choices:

- **For simple loading** (e.g. 1 container per day), *EUROPOEM II database (Professional pouring formulation from a container into a fixed receiving vessel)* in TNsG User guidance p.24 and TNsG version 2 p.66. Alternatively, M*&L model 4 (UK POEM)* in TNsG version 1 part 2 p.136, User guidance p.24 and TNsG version 2 p.66.
- **For repeated loading** (several containers per cycle), *Loading DEGBE* in BEAT (TNsG version 2). Alternatively: *Loading liquid* in RISKOFDERM Dermal model if influence of specific parameters (e.g. contamination, use rate) can be assumed and evaluated.
- **For smaller quantities** (< 1L), *M&L model 4 (UK POEM)* in TNsG version 1 part 2 p.136, User guidance p.24 and TNsG version 2 p.66 or *Mixing&Loading model 2 (HSL 2001)* in TNsG version 1 part 2 p.134, User guidance p25 and TNsG version 2 p.67, depending on quantities.

3. Liquid (semi-) automated tranfer/pumping				
Source	**Conditions**	**Indicative values : dermal**	**Indicative values : inhalation**	**Remarks Relevancy/Reliability**
EASE *Full containment, no direct handling*	Liquid Automated transfer	Very low	< 0.1ppm	Automated transfer/pumping without direct handling and in closed systems. EASE is not relevant to estimate dermal exposure. To be avoided
RISKOFDERM Toolkit *Connecting lines*	Liquid Automated transfer	Hands : 0.066 mg/cm^2/h *(0.92 mg/min)*		Considering small contamination and no exposure to body. Semi-quantitative model, to be avoided.
RISKOFDERM Toolkit *Loading liquid, partly automated*	Liquid Semi-automated transfer	Hands : 0.2 mg/cm^2/h *(2.8 mg/min)* Body 0.052mg/cm2/h * *(8.7 mg/min)*		Semi-quantitative model, to be avoided.
RISKOFDERM Dermal model *Loading liquid, automated or semi-automated*	Liquid Semi-automated transfer	Hands : 101 mg/min Body : 2.02 mg/min (95%ile)		Depend on product and conditions (use rate is an important parameter).
Mixing & loading model 7; TNsG part 2 p.142 (corrected)	Liquid pumping	*Total without gloves :* *138 mg/min* Under clothes and gloves : 1.38 mg/min	22 mg/m^3	Placing and connecting hoses + cleanup. Potential exposure calculated using a factor 100. Not mentioned in TNsG version 2. To be used carefully.
Handling model 2 – semi-automated handling of contaminated objects (nets) TNsG part 2 p.163 / User guidance p.26	Liquid Semi-automated transfer	*Hands on gloves :* *21 mg/min* Hands in gloves : 0.21 mg/min Body : 7.55 mg/min		It can be assumed that exposure while handling hoses is comparable to during handling nets. Potential exposure calculated using a factor 100.
BEAT : *Loading DEGBE*	Liquid Semi-automated transfer	Hands : 4614 mg/min Body : 18 mg/ min		Very wide distribution. Unrealistically high for automated transfer (but observed in practice).

Figures in italic are recalculated

*: considering that the front of the body (gross assumption: 1 m^2) is contaminated.

Comments:

- For automated transfer/pumping: The exposure during connecting lines would be very low or accidental. As it has been already done in previous dossiers (e.g. PT 21), we can consider the exposure during this task is negligible, or use results from RISKOFDERM *Connecting lines*.
- For semi-automated transfer/pumping: The exposure can occur while placing the hoses in the containers and receiving vessels and cleaning them. Values from BEAT's *Loading DEGBE* model are unrealistically high compared to other models: *Mixing & loading model 7* from TNsG and RISKOFDERM Dermal model. Data from *Handling model 2* are reported for comparison but is not relevant. *Mixing & loading model 7* provides actual exposure under gloves. The potential exposure is estimated using a factor 100. Values from RISKOFDERM Dermal model are dependent on the use rate.

Recommended choices:

- **For automated transfer/pumping**: Justify that the exposure is negligible compared to other related tasks, or use results from RISKOFDERM Toolkit *Connecting lines*.
- **For semi-automated transfer/pumping**: No relevant model in BEAT and TNsG version 2. Estimation can be done with RISKOFDERM Dermal model *Loading liquid, automated or semi-automated*, considering task conditions and use rate. *Mixing & loading model 7* is not recommended but may be used with caution.