EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Chemical Assessment and Testing

Agreed in TM I 2009

Ispra, 20/02/2009

HEEG opinion on Choice of secondary exposure parameters for PTs 2, 3 and 4

This document was prepared by FR in cooperation with HEEG.

Secondary exposure scenarios for several product types, like PT 2, 3, 4, 6, 18… (products in relation with surfaces disinfection/surfaces treatment) are similar:

- Dermal contact with treated surfaces (hard surfaces)
- Hand to mouth transfer, ingestion of residues arising from dermal contact

There are no appropriate models or worked examples available in the TNsG on Human Exposure (2002) concerning these scenarios applied to the disinfection of surfaces. However, models were found in ConsExpo and other databases: US EPA Standard Operating Procedure (SOPs) – Residential exposure assessment, HESI (Health and Environment Science Institute) Residential Exposure factors.

HESI has prepared a publicly available database and a Users Guide to address factors commonly used in residential exposure assessments. This effort is intended to be complementary to the US EPA's Exposure Factors Handbook and the Child-Specific Exposure Factors Handbook. The objective of the HESI database and associated Users Guide is to provide an electronic database with peer-reviewed data sets and interpretative guidance to support probabilistic residential exposure analyses.

For the same scenario, different approaches and parameters values have been found according to the databases. So, in order to harmonize the exposure assessment, we would like to discuss the approach that should be used and which values should be taken for the relevant parameters concerned.

1 - Dose calculation

In the following paragraphs, the different approaches found for the dose calculation are discussed.

1.1 – Dermal contact

1.1.1 – ConsExpo

The type of model used in ConsExpo is "Rubbing off". It describes a situation in which a surface (table top, floor) is treated with a product and dermal exposure arises from contact with the treated surface.

The external dose (quantity of substance deposited on skin) is calculated as follow:

$$\mathbf{D = S_{area} \times F_{dislod} \times Wf}$$

With $\mathbf{S_{area} = R_{trans} \times t}$

S_{area}: total area rubbed during exposure, calculated as the product of the transfer coefficient **R_{trans}** and exposure duration, limited by **S_{max}**, the total treated surface (m^2).
F_{dislod}: dislodgeable amount (amount of product applied on a surface area that may potentially be wiped off per unit of surface area) (kg/m^2).
Wf: weight fraction of a.s. in product.
R_{trans}: transfer coefficient (surface area treated with product that is in contact with the skin per unit of time) (m^2/s).
t: contact time (s).

1.1.2 – SOPs

This model provides a standard method for estimating dose for adults and/or toddlers after dermal contact with counter tops that have been previously been treated with pesticides. This scenario assumes that residues are transferred to the skin of an adult/toddler who comes in contact with treated areas such as floors and counter tops for recreation, housework, or other occupant activities. It can also be considered as a "rubbing off" model

The external dose (quantity of substance deposited on skin) is calculated as follow:

$$\mathbf{D = AR \times F \times Tc \times ET}$$

AR : application rate $\mu g/cm^2$
F: fraction of active substance on indoor surfaces that is available for transfer
Tc: transfer coefficient (cm^2/h)
ET: exposure time (h/day)

1.1.3 – HESI

No models have been found in the HESI database.

1.1.4 – Calculation and comments

In order to compare the different approaches, we made a calculation.
Considering an application rate of 0.01 g/cm^2 (layer of 0.01 cm with a product density of 1 g/cm^3), we obtained the following results[1]:

	SOP	**ConsExpo**
Transfer coefficient (R_{trans}/ Tc)	6000 cm^2/h	6000 cm^2/h
Contact time (t / ET)	4 h	1 h
Dislodgeable fraction (F_{disl})	10%	30%
External Dose (in-use product)	**24 g**	**18 g**

[1] The parameters used in the table are explained in the section 2 "Parameters" of this document.

Concerning ConsExpo and SOPs, we can see that the calculations are equivalent, considering that:

- R_{trans} x t = Tc x ET
- F_{dislod} = AR x F

The difference that we observed between the two external doses is only due to the values of the parameters used.

It is to be noted that the approach in some worked examples of the TNsG (e.g. for wood preservatives) is different, not taking into account the rubbed area and the contact time. This approach is not applicable for the considered scenario.

1.2 – Hand to mouth transfer

1.2.1 – ConsExpo

Dermal exposure of children can take place on uncovered skin, that is, on the head, the arms and hands, and on the legs and feet. Infant surface area exposed is calculated based on a child wearing short-sleeved shirt and a napkin, and no socks or shoes. The exposed area considered is, therefore, hands, feet; forearms and lower legs. The exposed area for dermal exposure is 1170 cm^2. To estimate the oral dose, in the ConsExpo "Cleaning products factsheet – Carpet powders", it is assumed that 50% of the product that ends up on the hands is taken orally. As the hands form about 20% of the total uncovered skin, this means that, via hand-mouth contact, 10% of the calculated external dermal exposure is ingested.

Once the dermal dose has been calculated, two models of exposure can be applicable for hand-to-mouth transfer.

Direct intake

This model describes uptake of the compound from a product that is swallowed at once.

The external dose is calculated as follow:

$$\mathbf{D = A \times Wf}$$

A: amount of product swallowed (kg)
Wf: weight fraction

Constant rate

This model describes a scenario in which the compound is taken over a certain period of time.

The external dose is calculated as:

$$\mathbf{D = R \times Wf \times t}$$

R : ingestion rate of the product (kg/s)
Wf: weight fraction of the compound in the product
T: time during which the product is being ingested (s)

The Direct intake model is the one used in the factsheet's examples of hand-to-mouth transfer.

1.2.2 – SOPs

The SOPs model provides a standard method for estimating incidental dose among toddlers from ingesting pesticides residues that have been transferred from indoor surfaces to the skin. This scenario assumes that pesticide residues are transferred to the skin of toddlers during post-application contact with treated indoor areas and are subsequently ingested as a result of hand-to-mouth transfer.

The external dose is calculated as:

$$\mathbf{D = AR \times F \times SA \times FQ \times ET}$$

AR: application rate (mg/cm^2)
F: fraction of active substance on indoor surfaces that is available for transfer
SA: surface area that contacts indoor surfaces and then transfers residues to the mouth in a given event (cm^2/event)
FQ: frequency of hand to mouth events (events/h)
ET: exposure time (h/day)

1.2.3 – HESI

Calculation is the same as the SOPs model.

1.2.4 – Calculation and comments

The direct intake model (ConsExpo) is the simplest approach, as it only considers the amount of product swallowed at once.

The approach by SOPs is a little more complex than ConsExpo because it considers the number of events and the exposure duration.

In order to compare these two approaches, a calculation has been made. Considering an application rate of 0.01 g/cm^2 (layer of 0.01 cm with a product density of 1 g/cm^3), we obtained the following results[2]:

	SOP	**ConsExpo**
Dislodgeable fraction (F)	10%	10% of the calculated external dermal exposure is ingested
Hand surface area contacting the mouth (SA)	20 cm^2/event	
Frequency of HTM event (FQ)	20 events/h	
Contact time (ET)	4 h	
External Dose (in-use product)	**1.6 g**	**1.8 g**

The results are very close from each other, even if the approach is not the same.

[2] The parameters used in the table are explained in the section 2 “Parameters” of this document.

2 - Parameters

The important parameters for these two scenarios are:

- the transfer coefficient (surface area treated with the product that is in contact with the skin per unit of time): $\mathbf{R_{trans}}$ or **Tc**,
- the fraction of dislodgeable active substance: **F**,
- the contact time: **t** or **ET**,
- the hand surface area in contact with the mouth: **SA**,
- the frequency of hand to mouth events: **FQ**.

Values have been found in the different databases, but they are somehow different from each others. Toddler/infant exposure is considered as a worst case.

	ConsExpo	**SOP**	**HESI**
Transfer coefficient	6 000 cm^2/h	6 000 cm^2/h	-
Dislodgeable fraction[3]	30%	10%[4]	-
Contact time	1 hour	4 hours	2 hours
Frequency of hand to mouth event	-	20 events/h	18 events/h
Hand surface area contacting the mouth	100 cm^2 (two palms)	20 cm^2 corresponding to 3 fingers	4.5 cm^2

For the **SOPs** (crack and crevice and broadcast treatment), it is assumed that there is a one-to one relationship between the dislodgeable residues on the indoor surface and the skin surface after contact (i.e., if the dislodgeable residue on the indoor surface is 1mg/cm^2, then the residue on the human skin is also 1 mg/cm^2 after contacting the surface).

The duration of exposure to indoor surfaces represents the mean of the 90^{th} percentile values for time spent in the kitchen and bathroom for toddlers (1-4 years).

HESI contains data on the frequency of hand-to-mouth events for children during indoor play. In a 2002 study, hand-to-mouth behavior in 72 children (37 male, 35 female) was examined. Children (11-60 months) were observed for 5-60 minutes per day for 1-6 days. Eating events were specifically excluded from the post videotaping quantitation of hand-to-mouth frequency. Children older than 24 months had a lower mouthing frequency than younger children. Therefore, only children below that age were considered for the present exposure assessment.

Observations of children by videotape and subsequent analyses have shown that the average hand area contacting the mouth is 4.5 cm^2 per mouthing event for 1-2-year olds.

The scenario in **ConsExpo** (cleaning product factsheet – carpet products) describes the treatment of fitted carpet in the living room. An area of 22 m^2 is cleaned with carpet powder.

The exposed area for dermal exposure is 1170 cm^2 and the hands form about 20% of the total uncovered skin.

[3] The TNsG 2007 presents values of dislodgeable fraction for several types of floor: 55% and 60% for white smooth and brown rough glazed tile respectively, 15% for non-slip vinyl flooring, 20% (dry hand) and 30% (wet hand) for cotton, knitwear, plastic, wood.

[4] The initial value of 50% has been reduced to 10% in the revision (2001)

For the contact time, it is assumed that a child (default 10.5 months) crawls over the cleaned surface for 1 hour a day during 14-day period.

3 – Conclusion

The different approaches and parameters have been presented above. After discussions between UK, FR, NL and DE, we came to the following conclusions: we think that both models (ConsExpo and SOP) are valuable and applicable. The choice of the model will depend on the scenarios and parameters available in the dossier. Concerning the parameters, we think that default values given for parameters that belong to a specific model should not be used for another model. In case-per-case, the experts can nevertheless adapt the values to specific scenarios, when relevant.