Recommendation no. 12

of the BPC Ad hoc Working Group on Human Exposure

New default values for indoor Transfer Coefficient

(Agreed at the Human Health Working Group V on 22 November 2016)

1. Introduction

The transfer coefficient (TC) is an exposure parameter used to describe the effectively contacted surface area per unit time leading to transfer of residue to the skin. The TC is originally used in an equation by US EPA (1997, 2012) to estimate pesticide exposure from treated surfaces and is used in the 'rubbing off' model of ConsExpo (Delmaar et al., 2005). The latter model is often used in the Biocides framework to assess the dermal and consequently possible oral exposure resulting from skin contact with treated surfaces. The TC has been subject to discussion as it is difficult to interpret, since it is not in fact a coefficient and underlying information to support the TC is scarce. Furthermore, together with exposure parameters such as the surface area contacted and duration of contact, the TC has a large impact on the exposure estimate. The scenarios for which the TC value is most frequently used is the post-application phase where children play on treated surfaces. Note that the US EPA (1997, 2012) derived TC values for a number of treated surfaces in outdoor and indoor situations. This recommendation only concerns the TC for indoor treated surfaces such as carpets or PVC floors.

In 2012, the US EPA updated their Standard Operating Procedure for residential exposure assessments. The TC value for children from 1997 of 6000 cm^2/hr was revised in the update to 1800 cm^2/hr. As the previous standard approach under the Biocides exposure assessment, referring to the 'rubbing off model', used the TC value from 1997, it was proposed to the Ad hoc Working Group on Human Exposure (HEAdhoc) to change the TC value in accordance with the US EPA in 2012.

2. Aim of the recommendation

This recommendation describes the way US EPA, in 2012, derived the new default TC value, describes underlying data, highlights some points for consideration, and finally provides a recommendation for a TC value default to be used in exposure assessments under the Biocides framework.

3. Discussion

In 2012 the US EPA derived the new TC value based on data from three exposure studies with in total four active substances (chlorpyrifos, pyrethrin, PBO and MGK-264), all in liquid formulations. Two exposure studies included a Jazzercise™ routine, which involves low impact aerobics movements, but with high contact activity for 20-min or 40-min by Selim (2004; confidential data and therefore the original report was not available for evaluation) and Krieger et al. (2000), respectively. A third study included scripted activities for 4 hours (Vaccaro 1991). The transfer efficiency of active substances from contacted surface, total surface contacted during an activity, intensity of contact and contact time are consequently aggregated into the TC value.

Brief description of the studies

In the Krieger et al., (2000) and Selim (2004) studies, a Jazzercise™ routine was performed to achieve maximum contact of the entire body with a surface using low impact aerobics movements. The potential dermal exposure was measured by using whole-body dosimetry. The TC values were derived using information on contacted surface, total surface contacted during an activity, intensity of contact and contact time linked with the potential dermal exposure. In the Krieger study, additionally biomonitoring doses were determined, but included data only for chlorpyrifos. The average biomonitoring dose was 3.3 µg/kg for 40 minutes of activity, or 0.08 µg/kg-min, where chlorpyrifos was used as an active substance on treated surfaces. The TC value for chlorpyrifos was 25,460 cm^2/0.33 hr (recalculated to match Selim results below). In the Selim study, adult males performed one 20-minute Jazzercise routine, which yielded transfer coefficients of 18,736 cm^2/0.33 hr for pyrethrin, 20,354 cm^2/0.33 hr for PBO and 21,572 cm^2/0.33 hr for MGK-264, showing very similar results for three active substances.

In the Vaccaro study (1991), adult males, dressed in bathing suits only, performed different activities over a 4-hour activity period. These activities included: sitting-playing with blocks, on hands and knees crawling, walking on carpet, laying on back, and laying on abdomen. Although activity was minimal during the last 2 activities, considerable surface area was in contact with the carpets during these times. In the Vaccaro study no TC values were derived, but instead biomonitoring doses were calculated for chlorpyrifos. In the Vaccaro study, the average biomonitoring dose was 12 µg/kg for 4 hours of activity, or 0.05 µg/kg-min.

Approach by US EPA to combine the studies

There is little data available on the transfer coefficients of active substances, therefore the US EPA combined the study results in order to obtain sufficient reliability in the derived defaults. The first link concerns the assumption that the Jazzercise routine is equal to the scripted activity in terms of the TC, despite they are different in time, activity and intensity of contact. It appeared that the biomonitoring data with chlorpyrifos in both studies by Krieger and Vacarro, i.e. 0.08 µg/kg-min and 0.05 µg/kg-min, resulted in the similar doses. The assumption is thus made that the transfer coefficient from a Jazzercise study was equivalent to what you would expect from the "typical" activity which is reflective of actual anticipated human behavior because of the shorter duration but intense degree of contact associated with its performance (i.e., Jazzercise cm^2/40 minutes = scripted cm^2/4 hours). Looking at the additional Jazzercise data from 20-min, it was not possible to compare biomonitoring doses, but it was noted that the exposure accumulation rates between the studies were similar (937 cm^2/min for pyrethrin, 1,018 cm^2/min for PBO, and 1,079 cm^2/min for MGK-264) for the Selim study and 1,273 cm^2/min for the chlorpyrifos study). Therefore, all Jazzercise studies were treated in the same manner regardless of duration. So, in using the available data, a general assumption that all high contact Jazzercise activity represented the available longer duration low contact activity was made. Therefore, also the Jazzercise cm^2/20 min = scripted cm^2/4 hours.

Based on the underlying assumption, the US EPA adjusts the individual TC values from all studies for 4 hours activity time by applying a factor of 0.25 to derive the TC as cm^2/hr. To make this adjustment, a fourth study, Ross et al. (1990) and Krieger et al. (2000) have shown for the Jazzercise routine studies that linear correction for duration was justified. Both Jazzercise routines were identical and produced similar results after linear time extrapolation. The 40 min exposure (13.8 ± 16.8 mg) and 20 min exposure (7.2 ± 3.8 mg) differs a factor of two and the aforementioned TC values are in close range, i.e. 937 to 1,273 cm^2/min. While linearity was shown between the two Jazzercise routines, this was not shown for the scripted activity in the Vacarro study. Possible steady-state situations of skin leading due to transfer are therefore not taken into account.

Applicability domain

All studies were performed with adults, therefore the obtained TC data requires an extrapolation to obtain TC values for children. US EPA applied a 0.27 reduction factor to the adult transfer coefficient, because of the differences of total body surface areas between adults and children (1 < 2 years old). The 0.27 reduction factor is the ratio between the total body surface areas.

In view of the limited dataset, questions may arise whether or not the TC values would apply to other types of active substances, formulations (e.g. dusting powders) and surface areas (e.g. walls). US EPA did not make any distinction and therefore the TC values would apply to other formulations and active substances for scenarios indoors. The default TC values for adults and children (1 < 2 years old) derived by US EPA are presented in Table 1.

Evaluation of the derivation of the TC values

The transfer coefficient is a complex parameter as it represents an aggregate of several processes (e.g. transfer efficiency from contacted surface, total surface contacted during an activity, intensity of contact) and seems hard to quantify properly from experiments. The US EPA presents a limited dataset with Jazzercise routines and scripted activities that should represent the contact adults and children may have with treated surfaces during work or play. Crucial assumptions made by US EPA are setting both 20-min and 40-min short high activity Jazzercise routines as equal to the longer scripted activity and the linearity of residue loading on the skin upon contact. Moreover, the defaults also apply to other active substances, formulations and contact surfaces, whereas the dataset is in fact too limited to do so. In addition, the translation factor from adults to children is based on the assumption that children have similar contacts as the scripted activity, hence only a correction for surface area sizes is needed.

The fact that the studies could be combined by either deriving very similar TC values or based on biomonitoring data provided sufficient confidence to consider the dataset as a whole. The TC values also showed that it seems reasonable to assume linearity, although it may be questionable if a steady-state is reached at some point as a result of saturation on the skin and possible removal of active substance from the skin. Applying a factor 4 on the TC values from the Jazzercise routines, may therefore not be the worst-case approach as initially the loading on the skin in the scripted activities may have been higher.

It is acknowledged that the data on TC are scarce. One additional study, not considered by the US EPA in their SOP, was found where potential dermal transfer of esfenvalerate to children was measured in a childcare centre (Cohen Hubal et al. 2006). The authors measured infant/pre-schooler dermal exposures the day after the floors were treated, summing up in total three times after treatment. The highest calculated transfer coefficients (median and range) of the infants were 1,700 (59–6,200) and pre-schooler 1,600 (56–5,900) cm^2/hr, respectively (see Table 2). These values, established after the first contact after treatment, are well within the range of the TC children US EPA calculated 1,300 (330–13,000) cm^2/hr. The fact that this additional study with a relevant target population showed results in the same range provides confidence in the approach and results obtained by the US EPA (2012).

Since the data on TC are scarce, the limited data available showing similar results, and alternative options to determine dermal exposure from dermal contact with treated surfaces are not available, it is recommended to follow the approach by the US EPA and to adopt the data provided. The approach is further supported by the results from Cohen Hubal et al. (2006).

To derive the TC values for infants, it is recommended to apply a correction factor for the contacted skin surface area. In the EU Biocide Products Regulation, infants (>6 to 12 months) are considered as the worst case exposed population for older children in the rubbing off scenario for playing on indoor treated surfaces, instead of the 1 to <2 year old children considered by US EPA. Therefore, the correction factor to extrapolate from adults to infants is determined by taking the total surface area of an infant (> 6 months to 12 months; 8 kg) and the total surface area of an adult, as described in the HEEG opinion 17 on default human factor values (2013). The surface areas are 4,100 cm^2 and 16,600 cm^2 for infants and adults, respectively. The correction factor calculated is 0.25.

According to the Biocide Guidance, it is suggested to take the 75^{th} percentile value from the distribution forward in the exposure calculations and to keep the other defaults exposure parameters as they are. The TC for infants is calculated as 7,800 cm^2/hour multiplied by the correction factor of 0.25; therefore, the TC for infants is established as 2,000 cm^2/hr. In any case, it is suggested to replace the default values by actual data where substance specific or formulation specific information is available.

4. Proposal for harmonisation

- It is recommended to update the indoor transfer coefficient default, thus taking the 75^{th} percentile value from the provided distribution for adults (US EPA 2012) and applying a correction factor of 0.25 for skin surface area as described above for children. This results in TC values of 7,800 cm^2/hr for adults and 2,000 cm^2/hr for an infant >6 to 12 months, respectively. For other children > 12 months the worst-case value of TC for infants should be applied.
- It is recommended to apply the defaults to all product types and formulations and to characterize the limitations of the approach in view of differences between the active substances, formulations used, and surface areas treated.

5. Acknowledgement

The HEAdhoc highly appreciated the help of US EPA in clarifying the assumptions and choices in the derivation of the Transfer Coefficient.

6. References

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7. Annexes

Table 1: US EPA (2012) distribution indoor surface transfer coefficient

Indoor transfer coefficients (TC; cm²/hr)		
Statistics	**Adults**	**Children 1 < 2 years old**
50th percentile	4,700	1,300
75th percentile	**7,800**	**2,100**
99th percentile	28,000	7,600
AM (SD)	6,800 (8,200)	1,800 (2,200)
GM (GSD)	4,700 (2.16)	1,300 (2.16)
Range	1,200 – 49,000	330 – 13,000

AM (SD): arithmetic mean (standard deviation)

GM (GSD): geometric mean (geometric standard deviation)

Table 2: Cohen-Hubal (2006) indoor transfer coefficients

visit	Transfer coefficient (cm²/hr)[a]
visit 1	
infants	1,700 (59 - 6,300)
Pre-schoolers	1,600 (56 - 5,900)
All children	1,600 (58 -6,100)
visit 2	
infants	1,200 (130 - 4,200)
Pre-schoolers	730 (78 - 2,500)
All children	940 (100 - 3,200)
visit 3	
infants	140 (13 - 2,800)
Pre-schoolers	82 (8 - 1,600)
All children	110 (10 - 2,200)

[a] Adjusted for potential transfer to hands and feet based on the study by Ross et al. (1990), in which approximately 40% of residue was transferred to garment on hands and feet.

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