Executive Summary

CEFIC-LRI project ETHZ-B7: Estimation of realistic consumer exposure to substances from multiple sources and approaches to validation of exposure models

Martine Bakker[1], Jacqueline W.H. Biesterbos[2], Bas Bokkers[1], Christiaan Delmaar[1], Tatsiana Dudzina[3], Nel Roeleveld[2], Paul T.J. Scheepers[2], Jacqueline G.M. van Engelen[4], Natalie von Goetz[3]

[1] RIVM, Centre for Safety of Substances and Products, Bilthoven, The Netherlands
[2] Radboudumc, Department for Health Evidence, Nijmegen, The Netherlands
[3] ETH Zurich, Safety and Environmental Technology Group, Zurich, Switzerland
[4] RIVM, Centre for Sustainability, Environment and Health, Bilthoven, The Netherlands

Project leader: Natalie von Goetz
Work package leaders: Martine Bakker, Paul Scheepers, Natalie von Goetz

Introduction

The project CEFIC-LRI-B7 aimed at deriving a tiered approach to aggregate exposure modelling for consumer products. A guidance for exposure modelling was developed and tested in two case studies for decamethylcyclopentasiloxane (D5) and triclosan (TCS). D5 is mainly used in cosmetics and personal care products (C&PCP) and triclosan is used in many different consumer applications such as C&PCPs and household cleaning products. A laboratory study with two cyclic siloxanes (D4 and D5) as pure substances and as ingredients of two personal care products (cream and deodorant) was performed to primarily study dermal uptake and secondly uptake by inhalation in human volunteers. A second guidance was prepared for human biological monitoring of consumer exposure. During the project both guidance documents were revised to include the experience obtained during the project.

Modelling

A conventional tiered approach was followed in modelling aggregate consumer exposure. The tier 1 model used literature information on the use of consumer products to determine (reasonable) worst-case point exposure values from single sources. These exposures were added up to yield a worst-case aggregate exposure. For the tier 2 assessment an ad hoc model was developed (PACEM: probabilistic aggregate consumer exposure model) that employs use data from 516 Dutch consumers (age 18-70) who completed an electronically distributed questionnaire. By constructing individual exposure profiles for each of the respondents a database on C&PCP use was constructed and coupled to the probabilistic exposure model. Thus, in combination with respective substance information this model can yield aggregate exposure levels for all substances present in C&PCPs.

In order to investigate the degree of conservativeness of the simple deterministic worst-case approach (tier 1) and the more refined probabilistic exposure assessment (tier 2) the modelling results were compared to the baseline measurements of D5 in end-exhaled air samples obtained in a laboratory study with human volunteers. To this end an existing physiologically based kinetic (PBK) model for D5 was adapted. A similar approach for modelling aggregate consumer exposure was followed for TCS, with the exception of human biomonitoring data being obtained from scientific literature rather than from a volunteer study.

Laboratory study

The experimental work included the assessment of human exposure to D5 and D4 (octamethylcyclotetrasiloxane) by collection of end-exhaled air samples in a group of 15 male and female volunteers. The cyclosiloxanes were collected on solid sorbent tubes and analysed using thermal desorption gas chromatography mass spectrometry (TD-GC-MS). In a first series of laboratory tests baseline exposures to D4 and D5 were determined following normal use of C&PCPs. In a second series of laboratory tests volunteers were asked to refrain from the use of C&PCPs for 24 hours. Next, they received standardized dermal exposure to D4 or D5 (pure substance) or a cream or deodorant or a combination of a cream and deodorant. To prevent inhalation exposure during these experiments, the forearm of the volunteer was placed inside a flow cabinet (exposure period). After removal of the pure substance or formulated product the participant was sitting underneath a fume hood, providing filtered air to prevent uptake by inhalation exposure.

Results and conclusions

The guidance was useful to serve as an organizer for the tiered approach to aggregate exposure modelling. It remains to be tested by other scientists.
Both the tier 1 and tier 2 model for D5 were reasonably conservative if compared to experimentally assessed baseline levels of exposure. For D5 the exposure estimates generated by tier 1 exceed the tier 2 estimates (95th percentiles) by two orders of magnitude, and the tier 2 estimates agree well with the baseline levels (i.e. realistic values). For TCS consumer exposure is overestimated by two orders of magnitude, presumably because the true prevalence of TCS in products is much less than the one assumed in the exposure modelling.
The laboratory study on dermal exposure showed that inhalation is much more important than dermal absorption for explaining the internal exposure of the studied cyclosiloxanes (either pure or as part of a C&PCP). Regarding exposure to self-applied dermal C&PCPs, there may also be a considerable contribution from products used by other persons in the same room or other confined spaces.