

## HUMAN EXPOSURE AND TIERED RISK ASSESSMENT (HETRA)

Request for Proposals (RfP) - Draft 20 May 2011, revised 14 July

### **Title: Characterising the nature of dermal exposure from consumer products and articles**

### **Project code number: B9**

#### **LRI strategic research area**

Complex environments

#### **Background**

Human exposure to substances is a consequence of their presence in the environment. In the case of substances that are used in consumer products and articles, direct dermal exposure occurs as a result of use of products and contact with the articles. Traditionally, estimation of exposure is achieved by focusing on the individual product or article that is the subject of the assessment. Recent international workshops like the IHCP<sup>a</sup>-ECETOC Workshop on “Exposure and Risk Assessment of Chemical Mixtures in Consumer Products<sup>b</sup>” and the US EPA “Exposure-Based Chemical Prioritization” workshop<sup>c</sup> have highlighted the paucity of good data that enable better estimations to be made of the true nature of dermal exposures. Such data are of three types.

- Knowledge on how the products and articles are used by consumers (habits and practices data).
- Physico-chemical properties of the substances and the products/article’s matrixes where they are present (e.g. migration rates, thickness of contact film, etc.).
- Actual experimental measurements of dermal exposure (e.g. external dose) properly conducted under relevant conditions that could be used for verification of modelled predictions.

Improvements in the understanding of those areas should lead to better strategies (including refined exposure models) capable of providing more realistic estimations of dermal exposures. In their absence, regulatory approaches necessarily embrace cautionary standpoints. For example, they typically aim to describe exposure conditions which might be associated with some ‘extreme’ use in order that it can be assumed to be protective of the whole population.

#### **Objective**

This project aims to improve the basis for how dermal exposures (in terms of skin loading rather than internal dose) to consumer products and articles are assessed by describing the nature of key exposure determinants (and, in turn, the characteristics of associated default

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<sup>a</sup> Institute for Health and Consumer Protection

<sup>b</sup> JRC, Ispra, Italy: 29-30th January 2009

<sup>c</sup> April 6-7, 2010 in Research Triangle Park, North Carolina

values) for dermal exposures to consumer articles/products. In particular, the project would be expected to:

- Analyse readily available data on relevant habits and practices of consumers, with particular reference to European populations, (e.g. ExpoFacts, Eurostat) in order to obtain accurate descriptions of current use. Available data would be compiled on a distributional basis in order to enable its use in both deterministic and probabilistic approaches. Habits and Practices databases like those currently available for a number of consumer product types (e.g., AISE<sup>d</sup>) should be taken into account and could be used as models. Although the focus of this research is not cosmetics, information that is available on cosmetics (such as that described by COLIPA<sup>e</sup>) should also be investigated concerning its ability to address certain project objectives.
- Using available databases to identify regional and other differences within and between populations and establish which of those differences is relevant taking into account the overall uncertainty of the exposure prediction.
- Determine the typical transfer factors (migration rates, thickness of surface contact films) for substances from products/articles to skin (compared to the typical default of 100), using both available data and simulated experiments in defined scenarios (such as those described by the commonly encountered REACH Product and Article Categories). It would be expected that this analysis would cover both 'new' and 'aged' products and articles, i.e. an analysis of the time course how exposure can vary, e.g. with 'new' and/or laundered and painted products, etc.
- Relate how the physico-chemical properties of substances (include grouping of similar materials) might be used to more accurately describe and predict dermal exposure, e.g. form of the product matrix, type of contact surface and characteristics. Commonly encountered exposure control strategies should be taken into account, such as the use of gloves during or hand washing after exposure, as well as the time-course following a use event (cf. first bullet).
- Define and undertake a series of simulated experiments, representative of actual exposure, covering relevant product/article forms, types and uses which would serve to verify the matrix/model & fill any data gaps.
- Identify any good distribution data as such (e.g. suitable for probabilistic modelling).
- Review the adequacy of currently applied exposure models/defaults.

## Scope

It is anticipated that this project will be structured and staged in a manner that ensures that the work products are regularly delivered and reviewed. It is also expected that any proposals are verified against a representative range of case examples (to be selected by the researchers in consultation with LRI), covering commonly encountered consumer products and articles. In the case of exposure modelling (preferably using existing models, with whatever refinements and improvements that may be identified), appropriate validation (including accuracy and precision and inter/intra subject variation) would be expected to be evaluated. It is expected that the findings will be developed into a peer reviewed publication, following a process that involves stakeholder discussion and presentation at a suitable scientific conference. This project would be expected to complement ongoing LRI and other

activities in the area. The successful research group would liaise with and take account of the findings and outcomes of such other work.

**Cost & timing**

2 - 3 years, € 400 - 500 K

<sup>d</sup> European Soap and Detergents Association

<sup>e</sup> European Cosmetics Association