Re: Docket Control number OPP 00578 and OPP 00579

Dear Administrator Browner:

The Children’s Health Protection Advisory Committee met on February 3-4, 1999 to consider, among other topics, the science policy issue papers being prepared as part of the implementation of the Food Quality Protection Act. The Committee and its Science Work Group appreciate the briefings provided by EPA both at this meeting and at its November 1998 meeting.

The purpose of this letter is to convey the Committee’s interest in, desire to learn more about, and initial comments on the science policy issues being addressed by EPA. Specifically, this letter raises questions about Issue Paper # 6, entitled “Standard Operating Procedures (SOP’s) for Residential Exposure Assessments.” Residential exposure is a very high priority in considering risks to children for several reasons. Exposure is at least as important as susceptibility in assessing risks of pesticides to children. The Committee is concerned that EPA has not adequately considered children in analyzing exposure issues, including but not limited to residential exposures. In addition, children spend most of their time in a variety of “residential” settings, which include traditional and non-traditional homes, childcare and schools. Thus, we consider this standard operating procedure to be critically important in itself, and as a benchmark in the way EPA will assess exposure to children.

Overall, the Committee’s comments are based on the following general themes and concerns:

- EPA should consider exposures and risks to children directly rather than as an extrapolation from adults.
- EPA should collect and use actual data on children’s exposures, rather than continuing to rely upon models that may seriously overestimate or underestimate actual exposures.
- It is important in assessing risks to children to take into account the full range of exposures due to environmental, social and economic variability.
- It is important in assessing risks to children to take into account the full range of behaviors, considering both development stages and individual variability.
Based on the Committee's underlying concerns, we are submitting the following questions as written comment, and look forward to the agency's response in writing and in the next version of this document. In addition, the Science work group intends to hold a special meeting to gather additional information from the EPA on how children have been specifically considered in these issues, and hopes to discuss these questions at that time:

1. Has variability in children's physiology and behavior (including both developmental stages and individual variability) been taken into account in the SOP's for residential exposures?
   a. It appears that the model uses average (mean) hand-to-mouth behavior to model ingestion. What consideration has the Agency given to a model that incorporates the full range of data on the variability of children's hand-to-mouth behavior?
   b. What is the known variation in non-occupational or residential residues due to geographic location? (e.g., does a household located in an agricultural community where farm fields are sprayed by air have consistently higher indoor air, dust and lawn residue levels?)
   c. Has EPA taken into account the nutritional status of children?

2. What data exists and what are the underlying assumptions built into (or not built into) the data sets?
   a. Has it been established that pesticide residue concentration in settled dust is more relevant than dust loading for measuring residential exposures to children?
   b. In assessing respiratory behavior, why has EPA not considered children's differences in the height from the floor, which result in different breathing zones for children as compared to adults?
   c. How is the non-occupational or residential exposure data being collected in studies (such as those conducted by the Indoor and Outdoor Residential Exposure Task Forces {IRETF and ORET}) being used in relation to or to validate exposure models?
   d. What human monitoring data is available about pesticide levels in children?

3. What is known and taken into consideration about the relationship between exposure and body burden (dose), and are these relationships adequately delineated and considered?
   a. Will pesticide exposure by inhalation (e.g. as the result of volatilization by showering and bathing) be considered in residential exposure assessment, and if so, in what way?
   b. Are there studies in addition to the IRET and ORET that have been conducted or are underway to measure non-occupational or residential
pesticide residues? Are the ORETF, IRETF, and other studies designed to give the information needed to measure children's exposures? If so, what additional data for children do they provide?

c. What plans does EPA have to conduct biomonitoring studies in children under different scenarios? (e.g. urban, rural non-farming, farming, etc)

d. What is the range of data that explores the relationship between exposure and body burden, the data suggested by b) and c)? Are these ratios adjusted for all relevant non-occupational exposures of children?

e. What specific plans does the EPA have or is it developing to prevent or reduce exposures to children by:
   1. education
   2. labeling
   3. best use practices
   4. notice of pesticide application
   5. modification of re-entry intervals

4. How will the consequent reductions in various exposures be measured and then factored into exposure measurement, analysis and modeling? How has this data been incorporated into the Standard Operating Procedures for children's residential exposures?

5. In light of the other considerations outlined above, what comprehensive epidemiological studies will EPA conduct regarding pesticide exposures to children from water, soil, dust and air in a residential environment? The Committee believes that such studies are necessary to fully integrate the various elements of exposure assessment.

The Children's Health Protection Advisory Committee remains very committed to supporting EPA's efforts to better protect the health and safety of children, and thanks you for the opportunity to comment.

Sincerely,

[Signature]
J. Routt Reigart, MD
Chair, Children's Health Protection Advisory Committee

cc. R. Trovato, P. Goode, S. Wayland, S. Johnson