

**SUMMARY REPORT
OF THE U.S. EPA COLLOQUIUM ON
SOIL/DUST INGESTION RATES AND MOUTHING BEHAVIOR
FOR CHILDREN AND ADULTS**

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1.0 BACKGROUND

The EPA/NCEA Exposure Factors Handbook provides a summary of the available statistical data on various factors used in assessing human exposure. The target audience for this Handbook is exposure assessors who need to obtain data on standard factors to calculate human exposure to toxic chemicals. These factors include: drinking water consumption, soil ingestion, inhalation rates, dermal factors including skin area and soil adherence factors, consumption of fruits and vegetables, fish, meats, dairy products, homegrown foods, breast milk intake, human activity factors, consumer product use, and residential characteristics. Recommended values are given for the general population and also for various segments of the population that may have characteristics different from the general population. Soil ingestion is one of the areas where data are limited. Several studies have been conducted to estimate ingestion of soil by both children and adults. The Exposure Factors Handbook summarizes soil ingestion studies conducted up to 1997, but several new papers have been published since then, causing the need for a forum to discuss these recent findings.

1.1 Purpose

On May 24-25, 2005, the “U.S. EPA Colloquium on Soil/Dust Ingestion Rates and Mouthing Behavior for Children and Adults” (Colloquium) was held at the Holiday Inn National Airport in Crystal City, Virginia. The purpose of the Colloquium was to convene an expert panel to assess the state of knowledge on soil/dust ingestion research for children and adults. Because mouthing behavior is closely related to children’s soil and dust ingestion, mouthing behavior research also was included as a major topic. The Colloquium was organized by Battelle with support from Horne Engineering Services. The Colloquium was designed to assist EPA in answering the following questions:

1. What is the state of knowledge on soil/dust ingestion and mouthing behavior?
2. Where should the state of knowledge be in order for EPA to make better decisions for the protection of children and adults from these pathways?
3. How can EPA and the scientific community advance the science (i.e., what research is needed)?

This summary report captures the major content of the presentations, breakout groups, and discussions/recommendations that occurred at the Colloquium. Presentation slides, organized sequentially by the order of presentation, the Colloquium agenda, and contact information of all the participants are included in this report as Appendices A, B, and C, respectively. This summary report was prepared by Battelle under contract with EPA and reviewed by the expert panel and EPA before it was finalized.

1.2 Expert Panel and Observers

The Colloquium was attended by an expert panel (see Table 1) consisting of ten non-EPA and nine EPA experts with broad experience and demonstrated expertise in the scientific areas related to soil/dust ingestion research and mouthing behavior. The non-EPA experts were selected through a review of relevant scientific literature, and represented a balance of academia, consulting, industry, state governments, and environmental organizations. Contact information for all the Colloquium participants, including the expert panel, is provided in Appendix C.

Table 1. Composition of Expert Panel

Non-EPA Expert Panel Members
Alan Stern, Dr.P.H., Division of Science, Research, and Technology, New Jersey Department of Environmental Protection
Bryce Landenberger, Ph.D., The Dow Chemical Company
David Jones, Florida Department of Health
Edward Stanek III, Ph.D., University of Massachusetts
John Kissel, Ph.D., University of Washington
Marcia Nishioka, Battelle
Natalie Freeman, Ph.D., Environmental Health College of Public Health and Health Professions, University of Florida
Pamela Bridgen, Ph.D., MBA, Environment International
Ramon Barnes, Ph.D., University of Massachusetts
Timothy Buckley, Ph.D., Johns Hopkins Bloomberg School of Public Health
EPA Expert Panel Members
Haluk Özkaynak, Ph.D., NERL
Jacqueline Moya, NCEA
Jeff Evans, Office of Pesticide Programs
John Schaum, ORD, NCEA
Marc Stifelman, Region X
Marian Olsen, Region II
Michael Dellarco, Ph.D., NCEA
Michael Firestone, Office of Children’s Health Protection
Paul White, NCEA

NCEA = National Center for Environmental Assessment

NERL = National Exposure Research Laboratory

While the Colloquium was not open to the public, several EPA employees with related research interests were invited to attend as observers, as was one special international guest of the EPA, Dr. Yasunobu Aoki of the Japan National Institute for Environmental Studies Research Center for Environmental Risk. In all, 26 EPA observers (listed in Table 2) attended the Colloquium.

Table 2. Colloquium Observers

EPA Colloquium Observers*			
Amina Wilkins	David Bussard	Marlene Berg	Steve Nako
Becky Cuthbertson	Gary Bangs	Mary Ballew	Talia Milano
Charles Smith III	Jace Cuje	Matt Lloyd	Ted Simon, Ph.D.
Dana Vogel	Jayne Michaud	Matthew Crowley	Thea Johnson
Dave Crawford	Jeffrey Soller	Michael Broder, Ph.D.	Wade Britton
David Hrdy	Laurie Schuda	Michele Burgess, Ph.D.	Zachary Pekar, Ph.D.
Denis Borum	Lynn Delpire	Shanna Recore	

*Refer to Appendix C for the Office or Region affiliations of EPA Observers.

2.0 INTRODUCTIONS AND BACKGROUND PRESENTATIONS

The Colloquium began on May 24th with an introduction, presentation of background material on existing and new research, and perspectives from various EPA Regions.

2.1 Welcome, Introductions, and Purpose

Mr. David Bussard, Director of NCEA-Washington, welcomed meeting participants. Mr. Bussard discussed NCEA's focus of providing tools for risk assessors. Mr. Bussard also reviewed the purposes of the Colloquium, namely to assess the current state of knowledge, provide information or data that are lacking, and identify actions to be taken to fill the data/information gaps. Mr. Bussard noted that the expert panel members had expertise ranging from human exposure researchers to those on the front lines of Superfund cleanups.

Ms. Jacqueline Moya, EPA NCEA, welcomed and thanked the participants and provided further explanation of the Colloquium's focus as described in Section 1.1 of this report. Ms. Moya noted that the Colloquium was not expected to result in recommendations for a specific value or distribution of soil ingestion, but to evaluate what direction the science needs to take in order to further the work occurring in this area.

2.2 Background on Existing Research and Modeling Techniques for Estimating Soil/Dust Ingestion

Dr. Haluk Özkaynak, EPA Office of Research and Development (ORD), presented "Background on existing research and modeling techniques for estimating soil/dust ingestion rates." The methods highlighted were tracer element mass-balance studies (cited as the most common) and microactivity-based physical modeling studies. Typical examples of each type of study were provided, along with a list of the method limitations for each study type.

For tracer studies, Dr. Özkaynak discussed age-dependent distributions and uncertainty for soil/dust ingestion. For microactivity-based physical modeling studies, Dr. Özkaynak discussed the time-use data involved, provided examples of macro- and microactivities, and highlighted the use of EPA's Consolidated Human Activity Database (CHAD, www.epa.gov/chadnet1). Dr. Özkaynak also described EPA/ORD/National Exposure Research Laboratory (NERL) Stochastic Human Exposure and Dose Simulation (SHEDS) model. This probabilistic model predicts the range and distribution of aggregate personal exposures and doses within a population as well as the uncertainty in the model estimates. Dr. Özkaynak provided summary statistic results for soil and dust ingestion rate simulations. Questions for Dr. Özkaynak focused on how the model treats short-term and long-term exposure, single events such as dropped food items, and transfer to hands for dust versus soil.

2.3 Regional Perspectives: Issues with Present Data

Ms. Marian Olsen, EPA Region II, and Mr. Marc Stifelman, EPA Region X, presented "Regional perspectives: issues with present data." Ms. Olsen covered the definition of Reasonable Maximum Exposure (RME), pathways of exposure, conceptual site models, receptors of concern, sources of exposure data, and research needs. The research needs highlighted by Ms. Olsen were (1) data on additional activity patterns; (2) geographically specific activity patterns; (3) age-specific activity data, i.e., for adolescents; and (4) concentration versus loading data for surface residues and dust.

Mr. Stifelman covered risk assessment applications, uncertainties and data needs, and the use of lead (Pb) as a tracer to illustrate direct soil and indirect dust exposure pathways. Mr. Stifelman described two non-residential scenarios that present challenges for risk assessment: (1) tribal subsistence, due to additional soil pathways, and (2) recreational exposure, with high soil and/or sediment contact rates and intermittent

exposures. A model of the assumptions made for direct and indirect exposure pathways at one specific site (Bunker Hill, Idaho) in terms of exposure to soil and dust was presented, along with challenges in assessing both exposure from sediments and exposure in a variety of climates and settings.

An extended period of questions and answers followed their presentations:

- In response to a question on examples of tribal activities that potentially increase exposure, Mr. Stifelman noted that the Iroquois process reeds with their mouths for traditional basket making. Also, a tribe in Connecticut wraps their fish in mud for cooking.
- Mr. Bussard asked whether the public focused on the RME for individuals at Superfund public meetings. The presenters responded that there is a great deal of variation in types of public input at such meetings; some ask for summary statistics of risk, while others express general concern and ask about being seen by a doctor.
- Panel member Dr. Timothy Buckley asked whether the EPA Regional Offices had plans to use the SHEDS model. The presenters responded that the Regional Offices are directed by Superfund guidance and headquarters initiatives, and therefore likely will wait for direction to use SHEDS from these sources. Another panel member noted that while SHEDS is a good tool, it cannot be used without the input of quality data gathered during human exposure projects with sound experimental designs.
- Panel member Dr. Alan Stern noted that staff working on site remediation need reasonable default values that they can apply initially across the board. Discussion followed on misuse of soil ingestion data, e.g., an exposure rate for one hour cannot be extrapolated accurately to a daily exposure rate.
- A panel member asked about contaminant distribution, and the presenters replied that they do not make assumptions, but they gather empirical evidence to define contaminant distribution.

2.4 Perspectives on Exposure Assessment Soil Ingestion and Pica

Dr. Ed Stanek, Biostatistics and Epidemiology Program, Department of Public Health, University of Massachusetts at Amherst, presented “Perspectives on Exposure Assessment Soil Ingestion and Pica.” Dr. Stanek covered routes of exposure (inhalation, ingestion [food, water], dermal absorption, and non-food ingestion), potential dose, and definition of exposure. He presented equations for exposure and daily ingestion, and noted that more focus needs to be placed on which term(s) one is trying to predict. Dr. Stanek noted that we want soil ingestion studies to directly measure exposure, and that much has been learned from past studies. He then presented the results of an example soil tracer methodology validation that assessed the recovery of various soil tracers by dosing adults with various amounts of soil. He discussed “noise” in the mass balance and noted that aluminum (Al) works as a tracer at higher levels of ingestion. Dr. Stanek also presented results using silica (Si) and other elements as tracers, and compared these with the Al results. Finally, Dr. Stanek highlighted the following challenges: (1) generalizing to whole populations from relatively small studies of individuals at discrete times (days) with no measure of intra-subject variability, and (2) separating the overall uncertainty into components of systematic bias, measurement error, and methodological bias.

During the question and answer period, one panel member suggested that if low recoveries were assumed and mathematical factors were applied to correct for these recoveries, the overall exposure results would be altered significantly. Other panel members discussed whether or not transit time is as important as the recovery of the tracer. One panel member noted that a recovery factor could be applied for an experiment of a given duration. A panel member also suggested standardizing the diet of subjects because diet affects

absorption. Another panel member noted the difficulty of performing duplicate diet studies because of the difficulty in getting people to collect true duplicate samples.

2.5 Characterizing Indoor/Outdoor Activity Patterns of Young Children

Dr. Natalie Freeman, University of Florida, presented “Characterizing Indoor/Outdoor Activity Patterns of Young Children.” Dr. Freeman noted that transcribed videotaped observations have been used to quantify children’s microactivities, and that microactivities typically are reported as hourly rates independent of where the child spends time. She noted that the best way to present, analyze, or make the best use of this rich source of data is not known. She presented data from the Rio Bravo Healthy Child Project, a longitudinal pesticide exposure study conducted over a two-year period with from 52 to 60 children. Dr. Freeman also stated that some children have much higher mouthing activity than others (data are not normally distributed). Also, the “high-end” mouthers are often the same both indoors and outdoors, and there is more inter-subject variability when children are outdoors. Dr. Freeman also posed questions such as: (1) What are the important age or temporal groupings for looking at behavioral data? (2) Are temporally adjusted variables (frequency/hr, percent time) what we should be looking at? (3) After how many contacts will a child’s hand reach its limit for surface loading? (4) How should rare events be treated? and (5) What measures are best for characterizing exposure as opposed to describing the child? In response to the presentation, one panel member asked about cultural versus universal practices. Dr. Freeman responded that many of the observed behaviors are universal although cultural and regional differences do exist.

2.6 Soil Ingestion in Children and Adults in the Same Family

Ms. Moya presented a summary of a recently completed study titled “Soil Ingestion in Children and Adults in the Same Family”, which had been conducted by Scott Davis *et al.* at the Fred Hutchinson Cancer Research Center (Seattle, WA) as part of a cooperative agreement with EPA. Ms. Moya covered background information, data collection, methods, and results. The study involved volunteers from a previous study and applied the trace element methodology to evaluate soil ingestion over a period of 14 days. The study involved collection and analysis of food, fecal, urine, and soil samples. Ms. Moya highlighted some of the results of the study including child and adult mean soil ingestion rates, the fraction of parents who had occupational soil exposure, and the fraction of parents who did housework, carpentry, or remodeling. Results specifically related to the tracer methodology data also were summarized by Ms. Moya. The correlation of the tracers Al, Si, and titanium (Ti) to samples of surface soil from a soil core were evaluated. Finally, the association of various activities such as eating unwashed foods, nail biting, hand washing, dirt eating, thumb sucking, furniture licking, and carrying around a blanket or a toy were evaluated with respect to the level of soil ingestion. Hand washing before meals was associated with higher soil ingestion rates. The explanation for this is that the hands were visually dirty before eating, therefore needing washing. The soil ingestion would have occurred before the hand washing. Also, children who were observed by their parents eating dirt had higher soil ingestion rates.

3.0 BREAKOUT GROUPS

The afternoon of the first day consisted of two breakout groups each led by an expert panelist from EPA. The breakout groups were instructed to respond to a specific set of charge questions, two of which were the same for both groups. One group focused on the pros and cons of microactivity data, and the other group focused on the pros and cons of trace element methodologies. Experts were preliminarily assigned to a breakout group based on their expertise, but were invited to switch to the other breakout group if desired. During the second morning of the Colloquium (May 25th), the breakout group leaders presented a summary of each group’s discussions. The information that follows reflects both notes taken during the breakout groups and the summaries presented on the second day. A copy of the presentation slides for the Microactivity Data Breakout Group Summary is included in Appendix A of this report. There were no summary slides for the Trace Element Breakout Group.

3.1 Microactivity Group Charge Questions and Summary Report

The microactivity breakout group was led Dr. Haluk Özkaynak and consisted of 12 people as listed in Table 3. Note that not all of the observers participated in the breakout sessions.

Table 3. Microactivity Data Breakout Group Participants

Non-EPA	EPA
Bryce Landenberger, Ph.D.	Dave Crawford
David Jones	Haluk Özkaynak, Ph.D.*
Marcia Nishioka	Jeff Evans
Natalie Freeman, Ph.D.	John Schaum
Pamela Bridgen, Ph.D., MBA	Mary Ballew
Yasunobu Aoki, Ph.D.	Michael Dellarco, Ph.D.

* Group Leader

The microactivity group addressed each of the charge questions. The following provides the charge questions and summarizes the discussion and/or recommendations in response to each question.

- 1. The EPA has recommended a set of age groups to be used when assessing children exposures. Are the raw data from the mouthing behavior studies available to EPA? Can the raw data from all the available mouthing behavior studies be combined in order to conduct analyses for the various age groups?**

The group noted that raw data from various mouthing behavior studies currently are possessed by different principal investigators, including some in other fields such as developmental psychology. The group suggested that new funding and opportunities to collaborate will facilitate data access and pooling of current data. Dr. Freeman stated that the amount of data needed currently is not available, and that other factors such as autism need to be considered to explain extremely high mouthing activity rates. Several group members agreed that more data are needed, particularly for the age groups of under one year and 6-21 years. One member noted that the National Children’s Study (a joint study of the U.S. Department of Health and Human Services and EPA, <http://nationalchildrensstudy.gov>) has an observational component and would be an ideal data source, especially for data on the first two years of life.

Another member stated that the real question is on the true variability of the data, including rare events, and posed the question “Who are we trying to protect?” This member also suggested that the nature of toxicity of the chemical needs to be considered. The questions to be answered are: (1) Do we have enough data to look at all age groups? and (2) Do we know how many children we need to study to understand the true range?

Specifically with regard to the age groups recommended by EPA, the following input was provided, primarily by Dr. Freeman:

- Very few videography records are available for children less than one year old. Data for 0-3 months may be available, but likely is in the developmental psychology field. There also are some data for 6-12 months, although this is for less than 20 individuals. There also are some parent observation studies (e.g., a study done in the Netherlands).
- The most data are available for ages 1-6 years.
- Data for ages 6-21 years are truly missing. During this period, children are in school and likely have very different behaviors than when they were younger and at home.

Dr. Freeman noted that studies can be combined, but consideration needs to be given to locations, methodologies, etc. Dr. Freeman stated that it is a matter of funding and getting the various principal investigators to work together and there also can be permission issues. Panelists noted that there are advantages and disadvantages of pooling data, but at least it provides the opportunity to see differences among data sets.

2. Is the ratio of ingested outdoor soil to ingested indoor dust an important consideration for exposure and risk assessments? Can this fraction be determined with existing information? Is it possible to differentiate particle size distributions for the exterior soil from those for indoor dust that adheres to hands?

The group noted that the ratio of ingested outdoor soil to ingested indoor dust is usually important, but understanding factors influencing exposure and risk also are important. The factors to consider include different types of exposures and chemical pollutants indoors and outdoors, along with track-in, resuspension, and fate and transport issues.

One member noted that the ratio of ingested outdoor soil to ingested indoor dust is not a single ratio, and emphasized that it is important to separately estimate each quantity. Another member indicated a lack of interior dust data broken down by seasonality. Mr. David Jones (Florida Department of Health) noted that being able to cite credible evidence that a certain family or community is at risk will elicit higher response rates in terms of mitigating exposure.

Dr. Özkaynak noted that the primary advantage of videography is that it allows the researcher to discern the most critical factors, which then helps risk managers to most effectively target cleanup. Dr. Freeman noted that such analysis requires frequent sample collection from children's hands. Ms. Marcia Nishioka, Battelle, added that for a past pesticide study, the results showed that the hands were completely loaded with dust particles by the seventh contact with surfaces, and that touching clean surfaces did not result in loss of residues from hands.

In terms of differentiating particle size distributions for the exterior soil from those for indoor dust that adheres to hands, the group noted that both house dust and soil can be affected by temperature and humidity (and soil can be wet). Another member noted that there is a strong need for study of transfer efficiency for different particulate materials and hand conditions. Dr. Freeman stated that as studies are repeated, the answer keeps getting smaller in terms of particles that adhere to hands. The group noted that indoor tracer and dust particles that are less than 100 microns are more critical to adherence to hand.

Mr. Jones emphasized the importance of gathering exposure data that are relevant for risk assessment. Mr. Jones noted that 6-month-old children do not tend to dig one foot down into the soil; therefore, data for this soil depth are not appropriate for risk assessment for a 6-month-old child. Another member highlighted the importance of a project manager consulting with a risk assessor before collecting data.

3. How can the relationship between residential indoor surface dust loading (mass per unit area) and total dust ingested best be assessed? How significant is this relationship?

Microenvironmental models like SHEDS are based on the hypothesis that indoor surface dust loading and total dust ingested are strongly correlated, although this needs to be tested by control studies and bio-monitoring studies. The relationship between residential indoor surface dust loading and total dust ingested can be assessed through physical microenvironmental modeling and by testing whether total dust ingested is a function of indoor surface dust loading. In order to isolate indoor surface dust in a tracer and bio-monitoring experiment, the substance used needs to be one that is present inside the home but not outside the home or in food. One member suggested using perfluorooctanyl sulfonate (PFOS)/

perfluorooctanyl acid (PFOA), although another member noted that these chemicals may get into food from Teflon pan coatings.

Dr. Pamela Bridgen, Environment International, noted that it is more important for a Superfund cleanup to achieve protective levels than to determine the breakdown of total exposure by exposure route. She added that the environmental community already knows to instruct people to clean their houses well, wash their vegetables before consumption, etc.

4. How can the accuracy, reliability, integrity, and precision of the available mouthing behavior studies be assessed?

The group noted that there have been studies looking at the “technician effect” (i.e., do two reviewers get the same results?). There is fairly good accuracy and precision in the transcription. The group noted the need to collect and analyze videography data consistently, but also identified some disadvantages of standardizing protocols at a preliminary stage. The major disadvantage cited is that standardizing protocols can eliminate some of the creativity in methods that is required to understand what works well and what does not work well. Dr. Freeman commented that videotape transcription protocols already are rather standardized, as it is a fairly small community of researchers conducting such studies. She noted that pen and pencil methods of transcription are yielding similar results to software transcription, and that much care has been taken to have duplicate transcribers to check consistency. Dr. Freeman also stated that collecting data consistently does not at all guarantee that the “right” data are being collected. Dr. Freeman noted that transcription methods need improvement.

The group also identified the need to evaluate reliability of videography data against other data sources such as hand skin wipe data. Dr. Freeman noted that it is typical to do no more than three hand wipes during an observational period, as too much hand wiping may interfere with a child’s typical behavior.

5. What are the appropriate ways of interpreting the existing mouthing behavior studies data? What is the best we can do with the data we presently have? How can we characterize and present the inter- and intra-individual variability and uncertainty associated with these data?

The group agreed that the full interpretation and best use of mouthing behavior studies data still need to be explored. There are very few longitudinal data available for children, and these data need to be analyzed to ascertain inter- and intra-child variability and uncertainty. One example that presents challenges in interpretation is when a child is moving between indoor and outdoor locations. Other questions to be answered are: (1) Do active children tend to be dirtier? (2) Do frequent mouthers also have high dust loading on their fingers?

The group noted that mouthing behavior data are very useful for exposure models, and that there is a need to correlate frequency of contact with direct hand loading measurements.

The group suggested pooled data analysis for inter-individual variability determination. One member noted that most studies are done only on one occasion per child, and that some studies (e.g., an Arizona study) attempted multiple days, but were not able to complete the study and generate defensible results. The group agreed that there are very few data available to examine day-to-day variation, noting that a Dutch study with infants is perhaps the only one.

6. A list of activity pattern-related research needs has been developed as a result of the Micro/Macro Workshop that was held in RTP in May 2001. Do these recommended projects adequately address the current activity-pattern research needs in the area of soil ingestion? If not, what research is missing and how should these studies be prioritized?

The group acknowledged the importance of the RTP workshop recommendations and highlighted the importance of prioritizing the research needs in terms of importance to exposure. One member stated that some of these research needs already are being addressed by current studies. Another member noted that topics that are known to be less important for exposure, such as seasonality, should be excluded from a research list (though some members disputed this point). Members also suggested additional topics for which information is lacking:

- Transfer efficiency (especially on quick and repeated touches, and over a variety of surface types)
- Relationship between transfer efficiency and surface loading
- Information on variation of dust levels in a room (typically only 4 dust samples are taken per room)
- Soil and dust composition (including consideration of whether it absorbs into organic materials such as components of curtains, upholstery, household appliances, etc.)
- Better techniques to collect data on indirect contamination of foods
- Direct ingestion by tribal members from beaches and wind storms.

7. What next steps are necessary to improve or fill data gaps in this area? List all the key mouthing behavior studies that should be included in an update to the Exposure Factors Handbook and Child-Specific Exposure Factors Handbook.

The group recommend including information on exposure factors for models such as SHEDS in the new Exposure Factors Handbook. The group highlighted the need to obtain, analyze, and include results from available microactivity studies (data collected by K. Reed, K. Black, J. Leckie, N. Freeman, M. K. O'Rourke, B. Eskinazi, and other children's centers). Several members stated that other data sources should be explored (e.g., Farm Family Exposure data or National Park Service data). Ms. Nishioka suggested that studies should be included on the role of psycho-social factors on activity behaviors, such as one journal article included in the pre-meeting materials describing how mouthing activity is related to a child's stimulation level. Group leader Dr. Özkaynak requested that group members make recommendations to him on the most important studies to include in the Exposures Factor Handbook. Ms. Mary Ballew, EPA Region I, suggested that the Exposure Factors Handbook should include an overview of the micro-exposure process to explain how the various components fit together.

8. What are the best methodologies for collecting microactivity data? Can standard protocols for the collection of microactivity data be developed?

In addition to videography, the group suggested radiofrequency chips and global positioning system monitoring, although it is unclear whether these methods will enhance existing methods. Improving technology can improve data collection, such as the use of digital video recorders that provide better resolution for closer focus on the details of individual contact events. Refer to the response to Charge Question #4 on standardizing protocols.

9. What technologies (e.g., fluorescent markers and others) are available to evaluate the results from videography or other techniques used to collect hand-to-object/surface, object-to-mouth, and hand-to-mouth contact data?

The group suggested bio-monitoring, hand wipes, and fluorescent markers as technologies that can be used to evaluate the results from videography or other techniques.

3.2 Trace Element Methodology Group Charge Questions and Summary Report

The trace element methodology group was led Mr. Paul White, EPA NCEA, and consisted of 11 people as listed in Table 4. The tracer methodology group began with an extended period of general discussion and then proceeded methodically through several of the charge questions, although not every charge

question was addressed individually. The following section provides the charge questions and summarizes the discussion and/or recommendations in response to each question. (An attempt was made to group information from the initial general discussion under the appropriate charge question below.)

Table 4. Trace Element Methodology Breakout Group Participants

Non-EPA	EPA
Ramon Barnes, Ph.D.	Jacqueline Moya
Edward Stanek III, Ph.D.	Marc Stifelman
Timothy Buckley, Ph.D.	Marian Olsen
Alan Stern, Dr.P.H.	Michael Firestone
John Kissel, Ph.D.	Paul White*
	Ted Simon, Ph.D.

*Group Leader

- 1. The EPA has recommended a set of age groups to be used when assessing children exposures. Are the raw data from the soil ingestion studies available to EPA? Can the raw data from all the available soil ingestion studies be combined in order to conduct analyses for the various age groups?**

The group agreed that because the sample sizes are so small (with the largest being about 100 participants) it is difficult to obtain information specific to subsets of age groups. To the extent that studies have been published on age variability, this does not seem to be a significant factor in exposure. This could be an area for collaboration with microenvironment modelers because even if there is uncertainty about absolute intake of soil, modeling provides information on variability by age group.

Dr. Edward Stanek, University of Massachusetts, noted that age information likely will come from the microactivity approach. Mr. White suggested that perhaps microactivity results can be used to prorate soil ingestion rates. Dr. Ted Simon, EPA Region IV, noted that there is as much uncertainty with the microactivity hand loading data as there is with tracer methodology data. Some members of the group requested that the data collected by the University of Massachusetts be made available to other qualified investigators so that there is less uncertainty about the reproducibility of the data evaluation.

- 2. Is the ratio of ingested outdoor soil to ingested indoor dust an important consideration for exposure and risk assessments? Can this fraction be determined with existing information? Is it possible to differentiate particle size distributions for the exterior soil from those for indoor dust that adheres to hands?**

Group members stated that it is primarily dust (residues that have settled on surfaces) that we are dealing with when incidental ingestion is concerned. Incidental ingestion of both indoor and outdoor dust occurs passively through surface to hand to mouth transfer when performing everyday activities. However, outdoor soil is more likely to be ingested during deliberate intake of soil dug up from the ground outdoors during playtime (children). Sometimes, for an assessment, one needs to know how much outdoor and indoor soil was ingested. There is a potential to tease out this information, but it is a complex area.

Dr. Stanek noted that outdoor concentrations of tracers can differ from indoor concentrations of tracers, and that using multiple elements provides multiple ratios/fingerprints that can be evaluated. Dr. Alan Stern, New Jersey DEP, stated that house dust varies considerably depending on where it resides, and that transport effects need to be considered. In addition, Ms. Moya noted that in the Davis study, results from surface and core soil, as well as house dust, were all fairly similar.

- 3. How can the relationship between residential indoor surface dust loading (mass per unit area) and total dust ingested best be assessed? How significant is this relationship?**

Dr. Stern stated that a New Jersey trace element study done with Chromium (Cr) suggests that surface dust loading is not a significant factor associated with total dust ingested. Furthermore, the study suggests that exposure to Cr was more closely related to levels of Cr in the urine. One member suggested that this does not sound consistent with other studies. Mr. White noted that concentration may be a better indicator of long-term conditions. He noted that a house can undergo a thorough cleaning which will impact the loadings significantly for a period of time. Presumably, the concentration would not change much over time because the sources of dust likely are the same; therefore, concentration might be a slightly better indicator. On the other hand, dust loading represents the current potential for contact with dust; and therefore, it is a valuable indicator of immediate risk of exposure.

4. How can the accuracy, reliability, integrity, and precision of the available soil ingestion studies be assessed?

The group generally agreed that trace element studies have the virtue of being observational studies that try to measure specific quantities of interest and use a methodology based on sound mass balance principles. However, there are many complications and complexities that prevent the data from being straightforward and easy to interpret.

Ms. Moya expressed concern that from the 1990 Calabrese study until now the soil ingestion results are continually dropping. She posed the question “What is the best tracer?”

Dr. Simon noted that while tracer studies are very appealing conceptually, there seems to be a big question of what actually is being measured. Dr. Simon pointed to inconsistencies that could be due to biological, physical, or chemical issues, and highlighted the importance of better understanding the inconsistencies. Dr. Stanek noted that soil is not that inconsistent from one area to the next, and is not likely the source of inconsistency. Dr. Stern noted that the statistical techniques necessary to draw significant conclusions from the tracer methodology data are complex and difficult to interpret. The necessity for such complexity raises questions about the robustness of the data. Members noted issues that may cause inconsistencies such as a “false” duplicate diet, inter-and intra-individual variability in transit time, missed samples, absorbance, bioavailability, etc. One member emphasized that in his opinion, tracer studies cannot be made more robust, and that we have gotten as much out of these studies as we can.

One member noted that the food/soil ratio is important, and that some tracers have been eliminated because of the large food/soil ratio. Another member stated that one should be able to use a multi-variant (or multiple-tracer) analysis in cases where there are factors that impact the concentrations of tracers. For example, children handling photographs could pick up trace levels of elements that would bias the exposure measurement. Microactivity data can help with evaluation of the tracer data. Members also suggested the possibility of using gold deliberately added to the soil as a tracer.

One member stated that transit time needs to be put into context, and that markers need to be used to mark the beginning and end of studies. Another member noted that bioavailability of the different kinds of Al or Si varies considerably.

Mr. Marc Stifelman, EPA Region X, endorsed the idea of using controlled soil. He stated that Pb should be considered from an isotopical standpoint, and that if transit time is important, then spiking a controlled diet seems like a reasonable approach.

Ms. Marian Olsen, EPA Region II, noted that there needs to be more interaction between tracer element and microactivity fields of study for common benefit.

Dr. Ramon Barnes, University of Massachusetts, stated that group study design would be beneficial. He cited the need for improved analytical methodologies and sampling methodologies (soil, dust, aerosols, etc.). He stated that pilot studies are needed to establish reliability of the technology and that more adult data are needed.

Dr. Buckley stated that the representativeness of the data is a big question, and there is large variability in the data. He noted that it is a good estimate over a period of days, but the uncertainty is large. He emphasized the importance of understanding how factors such as age, socioeconomic issues, and race impact soil ingestion rates.

Dr. Stern noted that studies of the half-life of chemicals in the body can be confounded because the chemical is being retained in the intestinal mucosa rather than actually being absorbed in the body. Dr. Simon stated that absorption or sequestering in the body and storage in the intestine could contribute to underestimates of soil ingestion rates. Dr. Stern noted that food tracers are less likely to be sequestered (as they are more soluble), which will result in an undercounting of soil.

5. What are the appropriate ways of interpreting the existing mass balance soil intake data? What is the best we can do with the data we presently have? How can we characterize and present the inter- and intra-individual variability and uncertainty associated with these data?

The group noted that the available data are useful for risk assessment. Mr. White summarized that the current focus of tracers is on Al and Si. Tracer element analysis using Ti yields some exceptionally high values that are difficult to understand. Also, while rare earth elements are appealing conceptually, they have been shown to have issues with detection and very high noise (i.e., high values that are not easily attributed to a particular source). Further attention should be given to Pb as a tracer because food levels are low, but environmental levels are high.

Mr. White summarized that the results should be interpreted as study period averages rather than daily results because of uncertainty. He noted that a mean would be an appropriate estimate across subjects, in which case the outliers would cancel each other out. Usually, soil ingestion estimates are applied across a long period of time; therefore, an estimate of the population mean may be better than any individual measurement. Concern was expressed by the group about not being able to evaluate the data with the same level of detail if averages were used.

Dr. Stanek stated that he is in the process of combining Davis, Stanek, and Binder data for a meta-analysis of the data in order to address the issue of age. He also noted that he has some experience with some of the other tracers such as barium and manganese, although each tracer presents its own issues.

Ms. Moya noted that ideally we would like to have a distribution of soil ingestion rates because of the use of probabilistic models. Mr. Stifelman suggested that perhaps the microactivity approach could help with the uncertainties for the tracer methodologies. Dr. Barnes suggested that China would be a good place to do a rare earth metals tracer study because of their high levels in soil and low levels in food.

6. What next steps are necessary to improve or fill data gaps in this area? List all the key soil ingestion studies that should be included in an update to the Exposure Factors Handbook and Child-Specific Exposure Factors Handbook.

The group concluded that there were three important next steps necessary to improve or fill data gaps in this area. First, since the Exposure Factors Handbook relies in part on the studies conducted by the University of Massachusetts, it would be preferable if the University of Massachusetts would make the raw data, used in several journal articles published over the past several years, available to EPA and other interested parties so that a more extensive peer review of those data can take place. Some questioned (non-specifically) the University of Massachusetts analysis procedures. Opening this data set up for a

thorough peer review would allow others to think critically about the results of these studies as well as consider alternative data analysis techniques.

Second, it would be valuable to conduct one study, including both microactivity and tracer components, using the same subjects over the same period of time. The group considered the fact that there may be some practical limitations about such a study, such as whether or not it would be reasonable to watch enough videotape to accurately evaluate a tracer study that would have to be done over a period of at least one week. Some of those logistical problems would have to be overcome, but a study like this seems like the next step to overcome some of the questions that remain about tracer and microactivity methodologies. Such a study should be planned in a group, such as the one gathered for this Colloquium, and the data should be publicly available so that a thorough peer review can be conducted.

Lastly, there is a need to define the most important endpoints required by people who use these exposure numbers, such as Superfund risk assessors. For example, is the most important data from high exposure children or an average across all children? Also, what is meant by the 95th percentile of exposed children? Does it refer to the distribution of all children, including those with pica, or does it refer only to the distribution of the non-pica children? Currently, those terms are not well defined, making it difficult for researchers in the field to supply the data needed by the risk assessors.

7. What are the best methodologies for collecting soil tracer element data for estimating soil and dust ingestion? Can standard protocols for the collection of tracer element data for this purpose be developed?

Several group members discussed the value and utility of screening methodologies to identify the high end of the distribution. Because the methodologies in use are so burdensome to the subject and expensive, the sample sizes are small and there are issues of representativeness. Perhaps screening diapers for high levels of Al and Si could be used to identify the high end of the distribution. Also, a few strategic questions could be asked of parents to flag particularly vulnerable children. One member noted that parent questionnaires have been tried and the results did not seem to be particularly accurate, so new methodologies would need to be tried (e.g., asking parents about a child's environment). One member noted that the regulatory position on pica has been ambiguous, in that pica is not directly addressed, but assumed to be covered with the high end of the distribution. It is not clear whether pica means regularly eating gram quantities of dirt by a small group of children, or every child occasionally eating large amounts of dirt, or some combination. Therefore, screening also would have to be combined with some sort of timescale measurement. Several members noted that it may be feasible to conduct trace element and microactivity studies jointly, to maximize the efficiency of recruiting and experimental plan development.

Dr. Stern noted that regulatory agencies are interested in the upper percentile, and that central tendency estimates are needed to calculate upper percentiles. Also, data that evaluated intra-subject variability would be helpful in evaluating the reliability of the tracer methodology. For example, sampling the same children at various times would provide an indication of whether or not the method was repeatable. Currently, most of the data are focused on inter-subject data, usually because of the number of study participants.

8. What technologies are available to evaluate the soil and dust ingestion estimates derived from tracer element mass balance studies?

The group discussed barium and manganese as possible tracers. Consensus was that they would not be useful for soil, but may be useful for food, because of the large amounts in food. Lanthanum, neodymium, and cerium were discussed, but their use as possible tracers was largely dismissed due to the fact that small amounts of contamination confound the data very easily. Considering soil particle size also was discussed as the concentrations of some tracers are dependent on particle size.

One group member suggested that because of China's high rare earth metal levels in soil (and surprisingly low levels in food), it may be a good place to do a study using those elements as tracers.

It also was suggested that soil could be seeded with an "ideal" tracer such as gold and studies could be performed using only that particular soil. However, it seems that seeding soil and still creating a somewhat realistic exposure environment may be difficult to accomplish.

4.0 CONCLUDING PRESENTATIONS AND RECOMMENDATIONS

Following the breakout group summary reports, as reflected above, there were two brief presentations and a general discussion on recommendations for future research.

4.1 Use of Existing Soil/Dust Ingestion Data and Methods

Mr. John Schaum, EPA NCEA, presented "Use of Existing Soil/Dust Ingestion Data and Methods." He posed the discussion questions: (1) How should existing data be used? (2) How can existing methodologies complement/validate each other? Mr. Schaum presented information on a validation exercise based on the methodology in *World Trade Center Indoor Environment Assessment: Selecting Contaminants of Potential Concern and Setting Health-Based Benchmarks*. This was prepared by Contaminants of Potential Concern Committee of the World Trade Center Indoor Air Task Force Group in May 2003. Mr. Schaum presented results of the ingested load versus surface loading and mouthing frequency.

Dr. Özkaynak noted that the SHEDS model has been compared to tracer study results, although this cannot truly be called a validation because we are unsure which, if any, numbers are correct. The SHEDS model and tracer study results are comparable in terms of general magnitude.

4.2 Research Needs

Dr. Michael Dellarco, EPA NCEA, presented "Research Needs" which was followed by a general group discussion on research needs. Dr. Dellarco noted that the challenge is how to accomplish everything that needs to be done. He highlighted two relevant requirements: (1) from OMB, research work has to have an impact and discernible benefit, and (2) from the mission of NCEA and EPA as a whole, our role is the improvement of risk assessment methodology.

For microactivity methods, he noted that the models need more data (input for model parameters and distributions for models) and that model validation is needed to gauge performance. For observations, improved activity pattern instruments are needed, and consideration needs to be given on how to categorize certain behaviors, the number of contacts leading to saturation, and food handling. For exposure estimates from observations, behavior is well characterized, but the relationship to exposure estimates is not clear. Also, there is a need to investigate whether study results can be broadly generalized, including transfer efficiency estimates.

For the trace element methodology, additional studies are warranted, along with a focus on the study protocol. Issues to be addressed include adequacy of collection duration post exposure, correlation of dietary input with fecal output, influence of dietary factors such as pH on retention, and reliability of duplicate diet procedures.

Dr. Dellarco's recommendations were to make existing data available for additional analysis to critique and publish protocols (including methodology limitations and additional recommended investigations), and as funds are available, to conduct more field studies.

Following the presentation, Ms. Moya opened the floor to discussion on ideas or thoughts on priorities.

One panel member noted that, in the short-term, a joint microactivity and tracer study should be a very high priority, although this should not be considered a model validation, but rather the addition of good data to the field of soil ingestion research.

Mr. Jones suggested a possible study for identifying high pica or high hand-to-mouth activity children. The study could be accomplished by collaborating with ongoing lead poisoning prevention programs and screening children with elevated blood lead levels as candidates for a videography study on hand-to-mouth activity. The videography study of these children would not inhibit their lead case management but rather would enhance it by possibly helping to identify the behaviors that are contributing to their lead poisoning.

Dr. Simon stated that the most promising tracers are the ones that occur in the lowest quantities in food. Therefore, studies on duplicate food samples and absorption issues are not as important because they will not make as big an impact for high-end soil ingesters.

Mr. Stifelman noted that the University of Massachusetts is conducting a meta-analysis of existing soil tracer studies, and it would be best if this could be done in a transparent way to make the best use of available data. This also may help build the case for collecting new tracer data.

Dr. Stern noted that we do not have a good handle on the biological processes involved (e.g., transit time from food to fecal/urine samples, absorption of tracers), and that this should be addressed before we proceed to more tracer studies.

Drs. Özkaynak and Stanek suggested that the first step should be taking stock of what we have and conducting a summary/pooled analysis of that in a transparent fashion. Another member noted the importance of making data available so that other people have opportunities to raise different kinds of explanations.

Ms. Olsen suggested that NIEHS, NTP, and CDC also are interested in different aspects of this, and there is potential for collaboration. We need to understand where they are or if they are doing studies that may provide helpful information.

One panel member noted that, given the interest in characterizing elevated exposures, we should examine existing data to see if we can characterize where we might find these children, then try to collect additional information on those children. Another member suggested that we define characteristics of pica behavior and screen a large number of children for possible pica and try to determine the proportion of the population that exhibits pica.

Dr. Landenberger suggested that more children over a broader geographic area could be done by working with county health departments. This could be a relatively inexpensive way of studying this behavior in various parts of the United States.

Another panel member stated that a longer-term priority is to focus on extrapolating short-term estimates to seasonal or annual estimates.

For identification of highly exposed populations, Dr. Simon suggested that a starting place may be communities such as the one in Ft. Valley, Georgia, where soil is ingested intentionally for minerals. Also, Dr. Bridgen noted that tribal children educated in the traditional lifestyle will have much higher exposure to outdoor soil. Dr. Simon also noted that he had reviewed environmental justice grants in Region IV, and that this could be another source of potential highly exposed subjects. Also, the

Association of State and Territorial Solid Waste Management Officials (ASTSWMO) may be a good source of subjects.

Dr. Freeman suggested that many autistic children are receiving methyl- B12 injections from their physicians to make them sleep better, and this could be increasing mouthing behavior in this population. There is some unsubstantiated evidence of this phenomenon in an ongoing study in New Jersey.

One panel member asked for input on the likely enthusiasm or lack of enthusiasm for future funding of soil ingestion work. Another panel member noted that the Superfund system is not set up for decision makers to see the value of studies because they are pressured to get the Record-of-Decision done quickly. It would be good if part of the budget at Superfund sites could fund these studies. Another panel member suggested getting on the schedule at the National Association of Regional Project Managers because they may want to know more about soil ingestion.

Dr. Kissel stated that the Superfund basic research program at NIEHS is more focused on environmental disease and that the program has expressed disinterest in soil ingestion studies. The member suggested that EPA should contact NIEHS about this problem. An EPA liaison to NIEHS noted that the NIEHS Superfund basic research program meets with EPA to discuss research priorities, and acknowledged the need to better educate principal investigators on research needs. It was noted that risk assessment is not an academic science in that data are usually lacking. Study proposals have been unfairly/mistakenly rejected in the academic community for a lack of information, even though a lack of information best recreates real-world conditions.

The Colloquium concluded with Ms. Moya thanking the participants for their attendance and active participation.

APPENDIX A

COLLOQUIUM PRESENTATIONS

APPENDIX B

COLLOQUIUM AGENDA

APPENDIX C

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