Comments on EPA's Probabilistic Assessment

of Children's Exposures

to CCA-Treated Playsets and Decks

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1 Introduction

On behalf of Arch Wood Protection, Inc., Chemical Specialties, Inc., and Osmose, Inc., Gradient Corporation has prepared these comments on selected issues identified in the September 25, 2003 draft final report prepared by the U.S. Environmental Protection Agency (EPA) entitled *A Probabilistic Exposure Assessment for Children Who Contact CCA-Treated Playsets and Decks Using the Stochastic Human Exposure and Dose Simulation Model for the Wood Preservative Exposure Scenario (SHEDS-Wood)* (the draft Exposure Assessment; U.S. EPA, 2003). As with the previous version of the SHEDS-Wood model that was provided for review by an EPA Scientific Advisory Panel (SAP) and the public in August 2002, the SHEDS-Wood modeling approach continues to be a complex exposure model that supports a number of detailed exposure analyses. As acknowledged in EPA's report, however, the model contains a number of uncertainties and data gaps for critical input parameters. In addition, in some cases, the model uses parameters that are likely to overestimate exposures. As a result, it would be premature to use the model to support risk management decision-making at this point in time. Moreover, the magnitude of the existing uncertainties inherent in certain key parameters (particularly for the more extreme percentiles of the distributions) is insufficiently emphasized in the draft Exposure Assessment. In particular, the presentation of certain input distributions gives the appearance that the exposure parameter of interest is better characterized than is warranted based on a review of the underlying data. The existing uncertainties underlying the model analyses should be better highlighted in the model documentation and should be recognized when characterizing and interpreting any results obtained using the model.

In particular, although substantial data (including data from studies specific for chromated copper arsenate [CCA]) have been incorporated into the model, data gaps exist for certain critical model assumptions, *e.g.*, the frequency with which children actually contact play structures or decks built of CCA-treated wood and affected soil in the vicinity of such structures. In some cases, the assumptions applied by EPA in the model do not best reflect currently available scientific data and biological mechanisms and are likely to overestimate actual exposures (*e.g.*, the assumed distributions for incidental soil ingestion and the approach used to estimate a gastrointestinal absorption "rate" from available animal study data). Only limited data exist for other important parameters (*e.g.*, certain elements of the hand-to-mouth transfer pathway for residue from wood surfaces) and questions exist regarding whether the currently available data adequately reflect exposure conditions likely to be present during children's activities on structures built of CCA-treated wood. Moreover, no analyses have been conducted to assess the plausibility of the combined exposure assumptions for this pathway and, as acknowledged by EPA, no suitable biomonitoring or other exposure data exist against which to independently validate the model results for specific pathways or for the overall exposure model.

The inherent model complexity also continues to raise concerns. In particular, some of the relatively sophisticated features of the model (*e.g.*, the ability to develop detailed time profiles of exposures and doses associated with specific materials for each individual) may not be particularly applicable to evaluations of exposures to wood preservatives such as CCA (*e.g.*, where long-term average exposures have been associated with the primary contributors to risk). Thus, the SHEDS framework may be adding levels of complexity which do not enhance understanding of the exposures and risks associated with specific materials of interest. Moreover, the degree of complexity incorporated in the model may exceed that warranted by the types of scenarios evaluated by the model and limitations in the precision of the available data. EPA should ensure that the complex structure of the SHEDS modeling approach does not impede implementation, interpretation, and review of the model results. The absence of biomonitoring or other data to validate the model results also raises concerns about the model complexity and the need for efforts to ensure the reasonableness of the model calculations.

Prior to using the model to support risk management decisions, the model results should be validated, *e.g.*, by conducting benchmark evaluations comparing model predictions with empirical data regarding specific model components or by validating the overall model results through use of biomonitoring data. Moreover, the model documentation should be modified to ensure that it accurately reflects uncertainties inherent in the model assumptions, *i.e.*, that such uncertainties are not obscured by the way in which the model documentation is presented, the way in which the uncertainty analyses are conducted, or the overall complexity of the model and its associated documentation.

2 Comments on Key Assessment Components

2.1 Model Documentation

The draft Exposure Assessment documents the specific numerical exposure values selected for use in the model in a more clearly organized format than was used in the earlier version of the model documentation that was provided for review in August 2002. The model documentation remains inadequate, however, in the amount of information that is provided justifying the specific choices made for each exposure parameter. For example, the model documentation typically presents the numerical distribution of values selected for use in the model and a reference for the underlying data source, if any. Information is not typically presented describing why that particular data set or reference source was selected, whether other alternative data sets are available, or why the selected values were chosen over alternative values. The draft Exposure Assessment also fails to discuss why specific distribution types were selected for use with a given data set, how specific distributions were derived from available data (*e.g.*, the approach used for normalizing the loadings data when deriving distributions for exposure point concentrations for residue), or how EPA concluded that it was justified to combine results from multiple studies (*e.g.*, to generate estimates of hand-to-mouth contact frequency).

To provide adequate documentation of the Agency's choices for input parameters, EPA should describe the spectrum of data that are available for each parameter and should justify that the selected data used to generate the exposure parameter distributions provide the most scientifically sound basis for each parameter. The documentation should also provide more detail regarding the process used to calculate the specified distributions based on the identified data sources. In addition, the documentation should address whether specific portions of the selected distributions may reflect varying degrees of uncertainty, *e.g.*, central tendency estimates of parameter values are often supported by a stronger technical foundation than are estimates of high-end percentiles of a distribution (*e.g.*, the 95th or 99th percentile). Such information is necessary to fully document the basis for EPA's modeling approach and to allow reviewers to conduct a complete review of the technical adequacy of the approach as well as the numerical validity of the generated results.

In several specific instances, documentation of certain data sources has limited availability. For example, EPA uses data from a report by Leckie *et al*. (2000) as the basis for distributions regarding the fraction of the hand surface area that is mouthed during each hand-to-mouth contact event and as one component of the basis for estimating the frequency of hand-to-mouth contacts. Only very limited information from this report was provided in EPA's August 2002 SHEDS-Wood documentation and no supporting information from this report was provided with the recently issued draft Exposure Assessment. Moreover, this report has not been made available for public review. Similarly, at least part of the basis for several parameters is attributed to personal communication with specific researchers or papers that are in preparation, *e.g.*, assumptions regarding bathing frequency, the hand-to-mouth dermal transfer fraction, and the frequency of hand-to-mouth contacts. Limited discussion of the information from these sources is provided in the draft Exposure Assessment. Ideally, these resources should be provided for review by the

SAP and the public; however, at a minimum, EPA should provide a more detailed discussion of the nature of the data obtained from these sources, the specific data that were applied, and how the distributions were derived based on the underlying data. Without this information, reviewers cannot complete a full review of the modeling approach or adequately assess the technical validity of EPA's proposed input values.

Another deficiency of the documentation presented in the draft Exposure Assessment is that the report frequently obscures the high degree of uncertainty inherent in many of the model assumptions. In particular, Table 12 (which summarizes selected aspects of the input values used in the modeling) provides a misleading view of the degree to which the input distributions are supported by directly applicable empirical data. While the "Comments" column of this table lists a specific data source for almost all of the parameters included in this table, professional judgment plays a substantial role in many of the distributions. In many cases, this role is not acknowledged in this summary.

For example, Table 12 indicates that the assumptions for the average fraction of residential and non-residential outdoor time that a child plays on or around a playset (on a day when the child plays on a playset) are based on diary data from the Consolidated Human Activity Database (CHAD). This listing suggests that the CHAD database actually contains data regarding the amount of time that children spend playing on or around playsets. The presentation of separate distributions for the warm and cold scenario also provides a misleading perspective regarding the level of detail inherent in the underlying data. In fact, as reflected in the draft Exposure Assessment, no data are available directly reporting the amount of time that children spend playing on playsets or, even more specifically, playsets built of CCA-treated wood.

Instead, based on the information presented in the text of the draft Exposure Assessment, it appears that EPA derived the distributions for these parameters by looking at the fraction of total outdoor time that is represented by time spent at a playground on days when playground activities were reported in the CHAD diaries. It also appears that, based on professional judgment, EPA assumed that this value was a surrogate for the fraction of time that a child would spend on a playset during outdoor play in a residential or non-residential location. Thus, the distribution derived from the CHAD diaries appears to reflect the relative likelihood that a child will play at a playground *versus* other locations rather than the relative likelihood that a child will play on a playset *versus* engage in other outdoor activities that do not involve playset contact. EPA has not provided any evidence to support the assumption that the data derived from the CHAD diaries are directly applicable for estimating the parameter of interest. The summary table should be revised to clearly indicate that these values are based on agency professional judgment as applied to CHAD diary data regarding the relative proportion of outdoor time spent at playgrounds.

Other similar instances should also clearly indicate the role of professional judgment in deriving the parameter values. For example, most of the parameters estimating the likelihood that a child may contact a CCA-treated deck or playset are not based on directly applicable data (*e.g.*, the fraction of children who have a CCA-treated residential deck), but instead are based on professional judgments regarding the applicability of other available data to this exposure scenario (*e.g.*, assuming that data regarding the prevalence of treated decks or other structures can be directly applied to estimate the prevalence of CCA-treated decks and structures). Similarly, as described in more detail below, the data applied by EPA to estimate the frequency of hand-to-mouth contacts reflect observations from a variety of indoor and outdoor activities which may not be directly applicable for estimating exposures occurring during outdoor play. Of particular concern is the use of indoor activity information to reflect behaviors occurring during outdoor play on a playset. Again, where the underlying data sets used to derive in the input distributions do not reflect direct measurements of the specific parameter of interest, both the summary table and the accompanying text should clearly indicate the assumptions and judgments that are inherent in using the underlying data to estimate the parameter of interest. Such an approach will provide a more accurate view regarding the critical assumptions and sources of uncertainties in the exposure analyses.

2.2 Exposure Point Concentrations

In the draft Exposure Assessment, EPA presents distributions for exposure point concentrations (EPCs) for arsenic and chromium. The distributions distinguish between concentrations in soil and wood surface residues and, in some cases, between concentrations observed for these materials associated with playsets and decks. In all cases, the distributions are lognormal and reflect data collected in a variety of studies.

In general, the data sets applied by EPA to develop EPCs appear to be applicable for the specific input distributions of interest; however, EPA's EPC distributions raise several questions. First, the data used to estimate arsenic and chromium concentrations in soil in the vicinity of playsets in the warm climate scenario are likely to overestimate actual exposures in this setting. Specifically, EPA used the results of study by Townsend *et al*. (2001; cited in the draft Exposure Assessment as Solo-Gabriel *et al*., 2001) to estimate these EPC distributions. In contrast to EPA's use of this dataset, however, this study focused on decks and walkways and did not collect any soil samples from below or near play structures. As a result, the data from this study may overestimate soil metals concentrations near play structures.

Soil metals concentrations below or near decks and walkways are typically greater than those near play structures for the following reasons:

- Decks/walkways typically have more horizontal wood surfaces exposed to rainwater, which is the primary mechanism for wood surface residues to migrate to underlying soils.
- Ground cover at a playground is replaced or amended more often than ground cover under or near decks and walkways.

Both the study authors (Townsend et al., 2001) and others (*e.g.*, Gradient, 2001) have characterized the study as an investigation that is indicative of conditions in the vicinity of decks. Moreover, EPA also uses the results of Townsend et al. (2001) study to estimate soil arsenic concentrations at decks for the warm climate scenario. Because these data may overestimate arsenic and chromium concentrations in soil in the vicinity of playsets, EPA should either identify a more applicable basis for this EPC distribution, adjust the distribution to reflect the reduced concentrations likely to be associated with playsets, or, at a minimum, acknowledge the likely overestimates of playset exposures associated with this distribution when presenting this distribution and interpreting results derived based on its use. In addition, the summary information presented in Table 12 should be revised to indicate that the study cited to support these data does not reflect data from soil in the vicinity of playsets, but instead reflects soil from the vicinity of decks which EPA has assumed is applicable to estimate soil concentrations in the vicinity of playsets.

Second, there is an apparent inconsistency regarding how data from a study by Stilwell (1998) are being used. For example, on p. 69, the draft Exposure Assessment indicates that the arsenic concentrations in soil near a CCA-treated deck for the cold climate scenario are estimated based on the results of Stilwell (1998). This choice appears to be appropriate because the study was conducted in Connecticut. The same study is also cited as part of the basis for the distribution of chromium concentrations in soil near a CCA-treated deck in the warm climate scenario. EPA does not provide any documentation regarding how data from the same study and conducted in the same location can be used to represent conditions in two different climates. Additional documentation is required in the text and summary table regarding the basis for these distributions.

Finally, EPA should provide additional justification regarding why wipe data from the CPSC (2003a) study were considered to be representative of a cold climate scenario. These data were collected from CCA-treated structures in the Washington D.C. area. Again, as for many of EPA's input distributions, additional information should be provided regarding the basis for EPA's choices and the process used to derive the selected values.

2.3 Transfer Efficiency Factors

EPA used data from the residue loadings studies to estimate transfer efficiency factors indicating the amount of residue transfer from wood surfaces to skin. To calculate the numerator in the transfer efficiency (TE) factor reflecting residue transfer to skin, EPA indicates that hand load data from the ACC (2003a) study were normalized by the measured hand sizes, and that hand load data from the CPSC (2003a) study were normalized by an average adult hand size. EPA also indicates that the denominator in the TE factor was calculated by normalizing the wipe data in both studies by the surface area of wood that was sampled. This approach is acceptable for deriving a transfer efficiency factor; however, a consistent approach must be used when applying these data to EPCs for residues on wood surfaces to estimate potential exposures. Specifically, the wipe data from these studies that are used to represent arsenic and chromium residue loadings on wood surfaces must also be normalized by the wood surface area sampled. If other loadings data are used in subsequent evaluations using the SHEDS-Wood model, similar constraints regarding the consistency of the approaches used to develop the EPCs for wood surface residues and TE factors will also apply. It appears that EPA has used a consistent approach in the calculations presented in the draft Exposure Assessment.

To reduce the uncertainty in estimating incidental ingestion and dermal exposure to dislodgeable arsenic and chromium, EPA should consider directly applying the hand load data from the ACC (2003a) and CPSC (2003a) studies into the exposure calculations. Such an approach would remove one additional step from the exposure calculation process. On p. 131, EPA presents an analysis confirming that similar results are obtained by using the hand loadings data directly in the model as are obtained by using a combination of wipe data and corresponding TE factors. If the hand data and TE factors are derived from the same underlying data sets, this finding would be the expected result. If other hand and wipe loading datasets are applied in the SHEDS-Wood model in the future, similar calculations should be conducted to confirm that the two approaches are comparable with respect to estimated exposures.

2.4 Soil Ingestion Rate

To estimate the incidental ingestion of soil by children, EPA uses data collected from studies of children in Amherst, Massachusetts and Anaconda, Montana (as presented in Stanek and Calabrese, 2000, and Stanek *et al*., 2001). EPA also relies on a workshop report regarding pica soil ingestion (ATSDR, 2001). The approaches used by EPA to derive and apply the distribution for this parameter raise concerns that are discussed below.

2.4.1 Development of the Parameter Distribution

While EPA is correct to update the basis for its evaluation of children's soil ingestion rates for the SHEDS-Wood model by considering more recent reports regarding this parameter (*e.g.*, Stanek and Calabrese, 2000; Stanek *et al*., 2001), significant concerns exist about the validity of the approach used to derive the distribution presented in the draft Exposure Assessment. Deficiencies in EPA's approach include the method used to calculate the representative soil ingestion distribution using the data from the Anaconda and Amherst studies, the choice to combine data for pica and non-pica children in developing this distribution, and the failure to adjust the available data when applying them to estimate long-term typical exposures based on short-term studies. Instead, children's soil ingestion rates should be estimated using a more accurate approach which does not combine the Amherst and Anaconda data sets, creates two separate analyses for pica and non-pica children, adjusts the data derived from seven-day measurements of soil ingestion to better reflect likely annual average exposures, and adjusts the data from the underlying studies to better reflect the age range of interest in the Exposure Assessment.

Based on the information provided in the draft Exposure Assessment, the procedure used to derive the soil ingestion rate distribution by combining the Anaconda and Amherst sites was not executed properly. In keeping with standard statistical methodology, the median ingestion rates from the Amherst and Anaconda sites can not be averaged to give a representative median value, *i.e.*, the medians from two lognormal distributions can not be arithmetically averaged to give a median for the combined group. Using the information presented in the draft Exposure Assessment, the correct combination of the Amherst and Anaconda data would have a median (or geometric mean) that would be lower than the value of 31 mg/day estimated by EPA. The true value for this parameter depends on the range of the distribution, which was undefined, but is estimated to be between 24 and 28 mg/day.

Another shortcoming of the soil ingestion distribution presented in the draft Exposure Assessment is the combination of information regarding pica and non-pica behavior in estimating a distribution for all children. The distribution presented in the draft Exposure Assessment implies that the complete soil ingestion distribution is supported by empirical data, including the incorporation of a pica level soil ingestion rate (*i.e.*, 500 mg/day) at a point between the 95^{th} and 99^{th} percentiles of the distribution. In fact, the likelihood of such an elevated soil ingestion rate appears to be far lower, based on the three most relevant tracer studies of children's soil ingestion (*i.e.*, Calabrese *et al*., 1989; Davis *et al*., 1990; and Stanek *et al*., 1999). In these studies, a rate at this elevated level was only observed in 1 of 200 children in only 1 of 3 weeks of the specific study in which it was observed. Thus, the present soil ingestion distribution used in the draft Exposure Assessment is overly conservative and will overestimate the upper end of exposures *via* this pathway. Therefore, the pica child should be excluded from the calculation of the non-pica children's soil ingestion distribution, especially as the pica children are already considered as a separate, special case in the exposure analysis. Furthermore, there are no data to support a statistically-derived soil ingestion distribution for pica children. Instead, it is more appropriate to make assumptions about the pica child exposures from sources such as ATSDR (2001) and to keep such calculations separate from the exposure estimates for the general population.

The draft Exposure Assessment also does not address the need to adjust soil ingestion rates based on short-term studies (*i.e.*, of approximately 1 week) to derive estimates of typical exposure over longer periods of time (*e.g.*, a year or more). The studies in Amherst and Anaconda monitored children over a seven- or eight-day period. However, the SHEDS-Wood model includes evaluations of longer-term exposures. This issue is particularly relevant in the context of calculating potential cancer risks associated with arsenic exposures. Stanek and Calabrese (2000) demonstrate how estimates for 95^{th} percentile soil ingestion rates based on short-term exposure will be higher than the true 95^{th} percentile of a longer-term average soil ingestion rate distribution due to uncertainty and day-to-day variability. Based on consideration of "regression to the mean," this reduction in the 95^{th} percentile over time can be estimated from variance components. Using a long-term adjustment factor, Stanek and Calabrese (2000) estimated that the true 95^{th} percentile long-term value for the Amherst population should be 124 mg/day, compared to the 95^{th} percentile seven-day average soil ingestion rate of 208 mg/day.

In deriving its soil ingestion rate distribution, EPA should also consider adjusting the data from the soil ingestion studies to reflect differences in the age group evaluated in the studies (*e.g.*, commonly in the 1-4 year old range) relative to the age group of interest in EPA's Exposure Assessment (1-6 years old). An approach for adjusting the study data is discussed in Gradient (2001). This approach is based on soil ingestion assumptions presented in EPA's Integrated Exposure Uptake/Biokinetic (IEUBK) model for assessing children's exposures to lead (U.S. EPA, 1994). Use of this approach would yield a 95th percentile estimate (reflecting long-term exposure) of 104 mg/day for children between 1 and 6 years old.

In light of the deficiencies in the approach applied in the draft Exposure Assessment, the appropriate approach for estimating soil ingestion rates should not combine the results of the Amherst and Anaconda studies and should include separate analyses for pica and non-pica children. In addition, the data from the underlying soil ingestion studies (reflecting short-term measurements) should be adjusted when applying them to estimate soil ingestion exposures over long-term exposure periods, and should also be adjusted to reflect the age range of interest.

2.4.2 Application of the Soil Ingestion Rate Distribution

Exposure estimates *via* soil ingestion are influenced by assumptions regarding the daily incidental soil ingestion rate and the amount of time spent by a child in contact with soil affected by releases of arsenic and chromium near CCA-treated wood decks or playsets. The calculation supporting both of these factors that determine soil ingestion are problematic. In particular, the mean daily soil ingestion rate is converted into a rate per hour spent outdoors by dividing the total soil ingestion rate by the mean time spent outdoors. The underlying data supporting the daily soil ingestion rate estimates, however, include a contribution to total soil ingestion that is derived from indoor exposures to dust.

Evaluations of the apportioning of total "soil" ingestion between outdoor soil and indoor dust have concluded that soil accounts for about 50% of the daily ingestion rate, while the other 50% comes from ingesting indoor house dust (based on soil ingestion studies by Calabrese *et al*., 1989). Similarly, EPA has used a comparable approach in its IEUBK model, where the default assumptions indicate that soil accounts for 45% of the child's daily soil ingestion rate and the remaining 55% is assumed to be derived from indoor dust ingestion (U.S. EPA, 1994). Based on these considerations, it would be more technically sound to convert the daily soil ingestion rate to an hourly soil ingestion rate using the waking hours for a child (*i.e.*, 12 hours) or some assumed partitioning between indoor and outdoor soil ingestion.

Presenting a soil ingestion rate based on waking hours rather than outdoor hours would reduce the hourly soil ingestion rate.

In addition, there are no empirical data directly supporting the assumptions made regarding the amount of time a child is exposed to soils near decks and playsets. During contacts with playsets, EPA states that it is assumed that children spend equal amounts of time on the playset and in contact with soil within 2 feet of the playset (*i.e.*, within the area of soil potentially affected by the treated wood structure). For contacts with decks, EPA assumes that children spend 90% of their time on the deck and only 10% of their time in contact with soil within 2 feet of the deck. In addition, EPA's calculations also include a factor indicating the fraction of time that a child plays on or around a playset or deck during an outdoor exposure event involving the playset or deck. On average, this fraction is assumed to be 75-80%, while the 75th percentile assumptions for this fraction are 98-99%. These estimates are likely to overestimate actual exposures in light of the limitations in the available data regarding children's actual exposures to CCA-treated structures and the potential for children to contact other areas within a residential yard or playground that are not affected by the treated wood structure during an outdoor play event.

It should also be noted that EPA defines what it means by "near" the playset or deck as being within 2 feet of the structure (p. 67). This area is assumed to represent the extent of soil around a CCA-treated structure that is affected by CCA constituents from the structure. The Agency cites studies by Stilwell (1998) and Degroot *et al*. (1979) as the basis for this assumption; however, the Stilwell (1998) study does not mention the lateral extent of soil contamination near a CCA-treated structure of any kind. Information regarding the extent of soil that is affected by treated wood structures can be found, however, in Malcom Pirnie (2001), Cooper (1990), and USDA (1980).

Another concern with the approach used by EPA to estimate incidental ingestion of soil is the misleading distinction that is drawn between the treatment of ingestion exposures from soil and wood residues. Specifically, the draft Exposure Assessment states that soil ingestion is considered to be "direct ingestion," while residue ingestion is assumed to occur through hand-to-mouth transfer. In fact, both exposure routes require the child to come into contact with the contaminated surfaces and exposure is likely to occur primarily through a similar underlying mechanism of hand-to-mouth transfer. This difference in approaches for estimating these two types of ingestion exposures leads to a further discrepancy in the assumed gastrointestinal tract exposure *via* each route, *i.e.*, soil ingestion is assumed to result in immediate GI tract exposure, while GI exposure resulting from residue ingestion is assumed to have a time delay. Presumably, EPA has developed this distinction based on differences in the available data for modeling each pathway rather than differences in the assumed underlying mechanisms of intake. EPA's documentation should, however, provide clarification on this issue. Additional related comments on this topic are presented in the section below discussing gastrointestinal absorption.

2.5 Hand-to-Mouth Exposure Pathway

EPA's draft Exposure Assessment observes that incidental ingestion of residue is consistently identified in the various scenarios included in its analyses as the most important exposure pathway for evaluating children's exposures to structures built of CCA-treated wood. This finding is consistent with the findings of numerous other exposure and risk assessments that have been conducted on this topic (*e.g.*, Gradient, 2001; CPSC, 2003b). A critical component of this exposure pathway is the assumptions made regarding how materials are transferred from the hands to the mouth.

In the revised version of the SHEDS-Wood model reflected in the draft Exposure Assessment, EPA continues to use a multi-step, mechanistic approach to estimate residue exposures occurring *via* hand-to-mouth transfer. This approach entails developing assumptions for numerous individual elements of the transfer process (*e.g.*, the amount of skin contacting the wood during a specific timeframe, the amount of residue transferred to the hands during a hand-to-wood contact, the frequency of hand-to-mouth contacts, the amount of skin entering the mouth during a hand-to-mouth contact, the time required to "saturate" transfer of residues on hands, and the fraction of the material removed from the hand during the hand-to-mouth contact). The amount of material that is available for incidental ingestion *via* this exposure pathway is also influenced by events that will remove residue from the skin surface after the initial exposure occurs, *e.g.*, hand washing or bathing, and associated assumptions regarding their frequency and efficiency.

Substantial uncertainties exist regarding appropriate values for many of these component parameters (particularly for use in assessing children's exposures to treated wood structures). As described below, several of the specific parameter distributions that EPA has proposed for use in assessing this exposure pathway are likely to overestimate actual exposures, particularly when applied to assess children's exposures to structures built of CCA-treated wood. Uncertainties also exist regarding the degree to which the results obtained using combinations of these uncertain parameters are likely to reflect actual exposures. Moreover, no directly applicable biomonitoring or other data are available for use to validate the model results and EPA has not presented any benchmarking analyses of the plausibility of the model predictions, *e.g.*, analyses that use other available empirical data (such as soil ingestion data) as a context for assessing the reasonableness of the model analyses. In light of the importance of this exposure pathway in determining children's exposures and risks associated with structures built of treated wood, it is particularly important that both the individual exposure parameters and the estimates resulting from combining these parameter assumptions appropriately reflect available scientific information and are subjected to rigorous analyses to ensure that the combined model assumptions generate reasonable estimates of potential exposures for this exposed population.

Comments regarding specific exposure assumptions and elements of this exposure pathway follow.

2.5.1 Fraction of hand and non-hand skin surface area contacting residues per unit time (rate per 20 minutes)

EPA's model includes assumptions regarding the fraction of the skin surface area (for the hands or other non-hand body parts that are unclothed) that comes into contact with the treated wood surface during a contact event. This fraction is used to estimate the amount of skin available for transfer of residue from the wood surface to the skin. The distribution of this parameter reflects data from a study in which a fluorescent tracer was used to evaluate soil loading on children at play (Kissel *et al*., 1998). EPA selected data associated with children playing in wet soil for developing the distribution used in the draft Exposure Assessment. Because no similar data are available regarding residue loading on children at play, EPA applied these data to estimate this parameter for both soil and residue contacts.

Consideration of the likely exposure conditions accompanying contacts with soil and residue suggest that these data are likely to overestimate residue exposures, perhaps by approximately a factor of 2 or more. Specifically, the soil used in the study and that children might encounter during play is more malleable material that has the potential to mold itself between fingers or to drift up and become deposited on skin surfaces not in direct contact with the soil surface. Moreover, during the Kissel research, the children were playing with toys (trucks and figures) and implements (a trowel and scoop), activities that would increase the potential for soil-to-skin contact. The use of wet soil in the experimental setting would also enhance the potential for soil to adhere to the skin in a way that is likely not comparable to the potential for skin transfer of residue from wood surfaces.

By contrast, the residue is present on a hard wood surface. As a result, the skin surface area which contacts the residue and is available for residue transfer is likely to be primarily limited to those skin surfaces which actually contact the wood surface. For hands, previous analyses have suggested that this value is likely to equal approximately 1/3rd of the available hand surface (U.S. EPA, 1999; Rodes *et al*., 2001; SCS, 1998, as discussed in Gradient, 2001). As a result, it is likely that the values used by EPA in the draft Exposure Assessment overestimate the actual skin surface areas that are available for transfer of residue from wood. For example, the distribution of values for this parameter for hands is centered in the 70-80% range. If the true value for this parameter is closer to 33% (*i.e.*, one-third of the hand surface area), this observation suggests that the values in this distribution should be reduced by approximately a factor of 2. The overestimate could be greater for casual hand-to-wood contacts. Similar concerns exist with regard to applying the Kissel *et al*. (1998) data to assess this value for non-hand skin surfaces.

2.5.2 Fraction of hand surface mouthed per mouthing event (unitless)

EPA's identified basis for its assumptions for this parameter is a videotape study of children's activities (Leckie *et al*., 2000). The report to EPA that describes this study and its results has not been provided for public review. Moreover, EPA has provided only limited information regarding the specific data from this study that were used to develop this distribution. In addition, EPA has not provided important contextual information from this study that is essential for understanding whether the data are applicable for the exposure scenario of interest in this instance and whether the distributions have been correctly derived. For example, EPA has not provided any information regarding the types of activities that the children were engaged in at the time of the videotaping activities or the degree to which hand-to-mouth contacts of varying intensity are reflected in the data used to calculate this distribution (*i.e.*, whether the data reflect a range of types of contacts or focused only on more intense contacts in which some portion of the hand was inserted in the mouth).

As described in more detail below, available studies indicate that the frequency of children's hand-to-mouth contacts varies depending on the types of activities engaged in (*e.g.*, such contacts are less frequent when children are engaged in active outdoor play than they are when children are engaged in quiet indoor pursuits). The available studies also indicate that the number of more intense hand-to-mouth contacts (in which some portion of the hand is inserted in the mouth) is only a subset of the total number of contacts that may occur (*i.e.*, some contacts that have been counted in some studies are only casual contacts in which the hand does not enter the mouth). It is essential that the data used to estimate this parameter be consistent with the choices made in deriving other related parameters. For example, if the data used to develop this parameter include only more intense hand-to-mouth contacts (*i.e.*, contacts in which some portion of the hand enters the mouth), it should be ensured that the assumed distribution for the hand-to-mouth contact frequency is based only on data for that type of contact (*i.e.*, that counts for casual touching of the mouth be excluded). Similarly, if the hand-to-mouth dermal transfer fraction (reflecting saliva removal efficiency) reflects more aggressive removal of materials from the skin surface (*e.g.*, as might occur during active thumb sucking), this distribution should not be applied to quantify exposures associated with more casual, superficial contacts with the mouth. Because EPA has not provided sufficient information regarding the basis of this parameter distribution, it is not possible to judge the validity of the underlying data, the distribution presented by EPA, or the ways in which EPA has applied these data.

2.5.3 Frequency of hand-mouth activity per hour

To estimate a distribution of values reflecting the variability in this parameter, EPA used a mix of data from 6 studies which reported information regarding children's hand-to-mouth activities. Four studies for which EPA was able to obtain raw data were used to derive a distribution of the variability of this parameter, while two additional studies for which EPA only was able to obtain summary statistics were incorporated into the uncertainty analysis. One of the studies used in the variability analysis is the Leckie *et al*. (2000) study that was also used to derive the distribution of values for the fraction of the hand that is mouthed during each mouthing event. As discussed above, this report has not been made available for public review and the limited documentation that EPA has provided regarding its use of this study is insufficient to assess the validity of the study data, the distributions derived by EPA based on these data, and the uses to which EPA has applied these data. Similar limitations hamper assessment of EPA's use of one of the studies applied in the uncertainty analyses (Black *et al*., 2003), which is an "in preparation" manuscript for which EPA has provided little description of the underlying data or the Agency's use of the data. Thus, a complete evaluation of the validity of EPA's assumptions regarding this parameter cannot be conducted because of limitations in the supporting information available for review.

Despite these limitations in documentation, it can be observed that the studies from which EPA has extracted data for use in this distribution reflect a mix of activity types and locations where activities were occurring. Table 2-1 summarizes relevant features of 5 of the studies considered by EPA in developing distributions for this parameter. As can be seen, the studies examined children's mouthing behaviors in a mix of indoor and outdoor settings and during a variety of active and quiet activities. A variety of ages are also represented in the available studies. Although available information is incomplete, it also appears possible that the studies may have varied in the types of contacts that were counted in determining hand-to-mouth contact frequencies, *e.g.*, some researchers may have counted any hand-to-mouth contact in determining total contact frequencies, while other researchers have provided information specific for more intense contacts.

EPA's description of the basis for the assumed distribution of values for this parameter provides no indication that any of the variations in the nature of the available data were considered when developing the distribution or that EPA evaluated the degree to which the available data were applicable for assessing the specific exposure scenario of interest in the draft Exposure Assessment. For example, data from one of the studies relied on by EPA indicates that a statistically significant difference exists in the frequency of mouthing behaviors observed in children ≤24 months old and those observed in children > 24 months old, with children in the younger age group exhibiting a frequency of such behaviors that is approximately twice that observed in the older age group (Tulve *et al*., 2002). EPA's distribution of values for this parameter does not appear to reflect any age-related distinctions in frequency of contacts.

EPA's documentation of this distribution also does not indicate that EPA ensured that the various data sets that were combined in deriving the distribution all reflected collection of the same type of data (*i.e.*, that the contact frequencies reflect counts of contacts of similar intensity). Some researchers (*e.g.*, Zartarian *et al*., 1998) have specified frequency counts for total hand-to-mouth contacts *versus* more intense hand-to-mouth contacts. Data presented by these researchers reported a frequency of more intense contacts that was less than one-third of the frequency of total hand-to-mouth contacts (Zartarian *et al*., 1997, 1998). Because the counts for more intense contacts reported by these researchers included consideration of insertion of non-hand skin such as the wrist into the mouth, the actual proportion of total hand-to-mouth contacts that is likely to consist of more intense contacts with the hand would be smaller. Because only the more intense type of contact is likely to transfer any significant amount of residue from the hand into the mouth, the distribution for this parameter ideally should only include data for this type

Table 2-1
Summary of Children's Videotape Studies

Study	Study Description	Activity Data Recording System	Locations/ Activities Studied	Notes
Zartarian et al. (1998)	Pilot study of 4 Mexican-American migrant children, 2-4 years old; 8-10 hours of tape/child (33 hours total); Salinas Valley, CA	Videotaping; questionnaires; activity tracking software	Followed children for approximately one entire day; indoor activities (e.g., watching TV, eating, napping, playing), outdoor play	Children in study spent 5-30% of the videotaping time in yards; report presents information specific for higher intensity hand-to-mouth contacts (e.g., inserting fingers in mouth).
Reed et al., 1999	20 Day care children (3-6 years old) and 10 children in residences (2-5 years old); videotape of waking hours for 1 day; 112 hours at day care; 56 hours at homes (5-6 h/child); northern NJ urban areas	Videotaping - focusing on child's hands and face (translated manually by 2 trained observers); questionnaires for home children	Information not provided	Did not report duration or intensity of hand-to-mouth contacts.
Leckie et al., 2000	Videos of 4 agricultural children (previously described Zartarian study population); 20 suburban children (1-6 years old), outdoor residential setting, San Francisco Bay Area, 1998/1999, 1-2 hours/child	Videotaping of activities, activity tracking software	Suburban children engaged primarily in outdoor activities (i.e., 78-100% of videotaped time outdoors)	Children in study spent 78-100% of videotaped time outdoors. Eight study children spent substantial amount of time at a park.
Freeman et al., 2001	19 Children (3-12 years old) particpating in NHEXAS study (10 children between 3-6 years old); videotaping (4 h/child); urban area of Minneapolis/St. Paul and nonurban counties; August/September 1997	Videotaping of activities, manual transcription of data; also used activity tracking software to translate 4 children's videos; time-activity diary; questionnaires	Indoor and outdoor activities; contacts w/nonfood items, hand-to-mouth contacts, touching various surfaces or objects	Observed age-related differences in behaviors, differences in hand-to-mouth contact activities when outdoors vs. indoors and active vs. inactive, and specific conditions leading to longer contact durations. Does not report detailed information regarding contact duration and does not report information regarding contact intensity.

Study	Study Description	Activity Data Recording System	Locations/ Activities Studied	Notes
Tulve et al., 2002	72 Children (11-60 months old) observed as part of a soil ingestion study;observed for 5-60 min/day for 1-6 days; Seattle, WA	Observations by trained observers	Active and quiet play; indoor and outdoor locations; daily frequency of mouthing contacts with hands, other body parts, surfaces, natural objects, and toys; frequency and duration of contacts	Observed age-related differences in behaviors, particularly for children <=24 months old and >24 months old. Data for children engaged in quiet play in outdoor locations or active play in indoors or outdoors locations were excluded from detailed analyses because the instances of such behavior were too limited in the study data

of contact. If such a distinction is not possible with the currently available data, the distribution for the fraction of the hand that is mouthed during each contact event should be adjusted, if necessary, to reflect the fact that some portion of the contacts reflected in the hand-to-mouth frequency estimate will involve mouthing of none of the hand or only a negligible portion of the hand.

Similarly, data from another of the studies reported a frequency of children's mouthing behaviors during active outdoor play that was approximately one-third less than that associated with quiet indoor activities (Freeman *et al*., 2001). Specifically, the average hand-to-mouth contact frequency observed during indoor activities was 4.7/hour for boys and 8.1/hour for girls, while the average contact frequency observed during outdoor activities was only 1.7/hour for boys and 2.3/hour for girls (Freeman *et al*., 2001). The mean value used in EPA's draft Exposure Assessment (8.45/hour) is greater than the frequencies observed during indoor activities in the Freeman *et al*. (2001) study and is comparable to the mean contact frequency observed during a mix of activity types in another videotape study (Reed *et al*., 1999).

Because contacts with outdoor structures constructed of treated wood (particularly playsets) are likely to occur predominantly during active play activities, this distinction is particularly important. Again, EPA's description of its derivation of the distribution for this parameter does not indicate that this difference in behaviors was considered. This distinction is particularly important because the potential for reloading of skin surfaces with residue only exists when the child is playing on or in the vicinity of the treated wood structure. Although a child may engage in a variety of types of activities after contact with the treated wood structure has ended (and thus a distribution reflecting a mix of activity types may be appropriate during the post-contact exposure period), a child is most likely to be engaged in active outdoor play activities during contact with the treated wood structures (particularly playsets). As a result, the distribution for the frequency of hand-to-mouth contacts during assumed contacts with the treated wood structures should reflect the lower frequencies observed during such activities.

Consideration of these data and the scenario of primary interest in the draft Exposure Assessment indicates that the distribution used by EPA for the frequency of hand-to-mouth contacts may be overestimated and should be refined to reflect differences in the frequency of such contacts related to age and the type of activity engaged in (*e.g.,* active outdoor play). EPA should also ensure that the distribution for this parameter (and the distributions for other related parameters such as the fraction of the hand that is mouthed during each contact event) reflect a consistent definition of a contact event, that is that the counted and modeled contacts represent a consistent intensity (*i.e.*, total contacts or only more intense contacts involving mouthing of some portion of the hand). EPA should also provide adequate documentation to describe the extent to which these factors have been addressed in the distributions used in the modeling. If these distinctions are not addressed, the resulting distribution is likely to overestimate actual exposures. For example, based on the findings reported in Freeman *et al*. (2001), if the distribution is derived using a combination of the available data that does not distinguish between contacts during active outdoor play and quiet indoor play, the frequency of hand-to-mouth contacts is likely to be overestimated for the contacts occurring during the critical period of actual contact with the treated wood structure.

2.5.4 Hand-to-mouth dermal transfer fraction

EPA has developed a distribution of values for this parameter based on data regarding the efficiency with which human saliva (used to moisten a piece of gauze) removed chlorpyifos from hands. Some of the information used to derive this distribution is attributed to personal communication with a researcher. Again, EPA provides almost no information regarding the nature of this communication, thus impeding effective review of EPA's modeling approach.

Several features of this distribution and the cited study underlying its derivation suggest that this distribution is likely to overestimate exposures that may occur during children's hand-to-mouth contacts. First, the experimental procedure used in the Camann *et al*. (1995) study cited by EPA to support this distribution involved wiping the hand surfaces with a moistened piece of gauze. Although the specific study cited by EPA was not available for review in preparing these comments, review of other work by these researchers suggests that the wiping activities were deliberate and thorough (*e.g.*, Camann *et al*., 2000). While some hand-to-mouth contacts may include sustained presence of some portion of the hands in the mouth, other contacts are likely to be more ephemeral and are likely to involve less efficient removal than attained in the experimental setting. Based on results comparing the removal efficiency of wipe materials *versus* the skin on hands, the use of gauze as the wiping material might also tend to overestimate the removal of materials by the lips or tongue, particularly for less intense contacts. Thus, this distribution is likely to overestimate exposure for some actual exposure conditions.

The likelihood that this distribution will overestimate actual exposures is also indicated by comparing the distribution for this parameter with those for hand-washing and bathing removal efficiency. For example, the mean value for the dermal transfer fraction (0.780) is approximately equal to (and slightly greater than) the mean value assumed for bathing removal efficiency (0.770) and is substantially greater than the mean value assumed for hand-washing removal efficiency (0.593). (This value is also greater than the maximum saliva removal efficiency assumed by EPA in the previous proposed documentation of the SHEDS-Wood model [0.50], based on the same underlying study by Camann *et al*.) It is unlikely that, on average, the unintentional removal efficiency associated with hand-to-mouth contacts reflecting a range of intensities would be greater than the average intentional removal efficiency associated with hand-washing or approximately equal to the removal efficiency associated with the type of sustained contact with the removal liquid that would occur during a bath. These observations indicate that the distribution for the dermal transfer factor should be re-evaluated to ensure that it reflects a reasonable set of assumptions for the range of exposure conditions that may arise during children's hand-to-mouth contacts. EPA should also provide more detailed documentation of the basis for this distribution.

2.6 Gastrointestinal Absorption

To estimate the gastrointestinal (GI) absorption of arsenic from residues and soil affected by CCA-treated wood structures, EPA has used the results of two recent animal studies by Casteel and co-workers (ACC, 2003b, c). While these studies represent the most scientifically-sound source of information that is currently available regarding GI absorption of arsenic from these sources, certain elements of EPA's use of these data in the SHEDS-Wood model appear biologically implausible or require additional documentation. In particular, EPA's incorporation of time into the absorption process (for both arsenic and chromium) raises several concerns, and could overestimate exposures. In addition, as with many of the other input parameters for the SHEDS-Wood model, EPA should provide better documentation regarding how the specified distributions were derived based on the identified data sets. Finally, the presentation of the supplemental analyses conducted using a worst-case absorption assumption mischaracterizes the nature of the calculation and the underlying data. As a result, the description of these calculations should be revised. These issues, as well as other specific comments identified in reviewing the exposure assessment, are discussed below.

2.6.1 Assumed Role of Time in GI Absorption Processes

EPA has used the absorption data generated in the Casteel studies and has transformed them into hourly absorption "rates" by dividing the absolute bioavailability values by 12. This approach reflects an assumption that 12 hours is the average interval between ingestion and voiding (p. 34). Within the context of the modeling approach, this assumption may lead to overestimates of exposure following ingestion. In particular, EPA's modeling approach (p. 29) states that a daily void is assumed to occur at 6 AM on each day (*i.e.*, 1 void per each 24 hours). Use of a 12-hour average absorption time and a void time at 6 AM implies that half of the ingestion events would occur after 6 PM on the preceding day, an exposure pattern which is clearly unlikely. As a result, it appears that typical exposure periods for ingested materials would extend beyond the assumed 12-hour time frame. In such instances, use of the hourly absorption "rates" derived assuming a 12-hour exposure period would overestimate likely actual absorption exposures.

Because this approach does not reflect any underlying biological information, if EPA chooses to retain this approach, the Agency should also clearly state in the Exposure Assessment documentation that the value obtained by dividing the absolute bioavailability value by 12 hours does not result in a biologically-based rate constant for GI absorption. The relative bioavailability adjustment (RBA) factor values determined by Casteel *et al.* in the ACC 2003 studies indicate the relative amount of arsenic in an administered dose of soil or residue that is absorbed compared to absorption of a soluble form. These RBA values have no explicit time component. Instead, the RBA is the amount absorbed in whatever time it takes for the bolus of administered material to travel through the portion of the GI tract where the material is absorbed.

It is not stated in the Casteel et al. study that the GI transit time in the pig is 12 hours. If EPA has such information, it should be provided in the Exposure Assessment. A study of orocecal transit time in human children indicated values ranging from approximately 3 to 7 hrs (Van Den Driessche et al., 2000). Orocecal transit only includes the portion of the GI tract from the mouth to the start of the large intestine (i.e., the cecum). Because most of the arsenic absorption will take place in the small intestine (Pott *et al.*, 2001), the exit of the material from the small intestine would be a more appropriate place to "stop" exposure than voiding from the terminal section of the colon.

EPA's approach for assessing the impacts of GI voiding on absorption also raises questions. For example, Figure 8 of the draft Exposure Assessment shows the effect of the GI tract void as a sloped line, implying that exposure decreases linearly over the course of an hour. Because the void will be a relatively instantaneous process, it seems more reasonable to model the exposure as falling vertically to the x-axis.

There is no sound scientific basis for EPA's choice to use different approaches to model the GI absorption of dislodgeable residue and soil. As noted above in the discussion of incidental soil ingestion, the mechanisms of incidental ingestion leading to GI absorption of these materials should involve nearly identical processes, *i.e.*, adherence of fine particles to the hands and fingers, mouthing of the hands, swallowing of particles, and absorption in the GI tract. Ideally, they would be modeled in a similar fashion because there do not appear to be any physiological or physiochemical reasons for using different approaches for these two exposure pathways. Because the difference in modeling treatment more likely relates to parameter constraints (*e.g.*, availability of data on soil ingestion rates *versus* the use of a mechanistic hand transfer calculation for assessing dislodgeable residue), if this approach is retained, the text should clearly identify this distinction as one related to modeling approaches rather than to theories regarding the underlying mechanisms of these exposure pathways.

2.6.2 Derivation of Distributions for GI Absorption of Arsenic

On p. 63 (Table 12) as well as in the text on p. 76, EPA indicates that beta distributions were fit to the data from the ACC bioavailability studies. EPA should provide a test statistic to demonstrate the goodness of fit of the distribution to the data. Also, EPA should provide more information regarding its basis for selecting the beta distribution as the proper distribution for this parameter.

On p. 76, EPA provides the characteristics of the beta distributions for GI absorption used in the SHEDS-Wood model. Although the data collected by Casteel *et al.* (ACC, 2003B, c) are cited as the basis for the values, EPA does not describe how the beta distributions were calculated from the underlying data. As shown below, the mean values reported in ACC (2003b, c) do not match the means or medians of EPA's beta distributions:

Estimates of GI Absorption of Arsenic

	EPA	Casteel et al. (2003)
Dislodgeable Residue		
Mean	0.273	0.29
Median	0.264	
Soil		
Mean	0.467	0.49
Median	0.467	

EPA should provide additional documentation of its calculations.

Comparison of EPA's distributions with the underlying studies reveals other discrepancies as well. For example, Casteel et al. (ACC, 2003b, c) reported a narrower confidence limit on the mean for the RBA factor for arsenic in dislodgeable residue than for the RBA estimate for arsenic in soil. Specifically, in the Casteel study, the values for the dislodgeable residue RBA are a mean of 0.29, with a 90% confidence interval (CI) from 0.26 to 0.32, while the values for the soil RBA are a mean of 0.49, with a 90% CI from 0.41 to 0.58. In EPA's Table 52, however, the distribution for the dislodgeable residue GI absorption (with a mean of 0.273 and a 95th percentile of 0.459) appears wider than the distribution for the soil GI absorption (with a mean of 0.467 and a 95th percentile of 0.631). This difference between EPA's distributions and the underlying study analyses should be explained.

2.6.3 Presentation of Supplemental Analyses of Absorption

On p. 76, EPA states that a residue GI bioavailability value for arsenic of 100% was used as a "bounding scenario" in a special SHEDS-Wood analysis. Within the same section, however, the data of Nico et al. (2003) are cited indicating that the arsenic-chromium complex in the wood is insoluble. In light of these data, it would be better to describe the evaluations using the 100% value as a parameter sensitivity analysis, and not refer to it as a bounding estimate which implies that such a value is supported by empirical data. Similarly, the discussion of the results of the analysis using 100% GI absorption for dislodgeable residue (p. 117) should reiterate that the 100% value was assumed for the purposes of the sensitivity analysis only and that the scientific studies suggest a much lower value is accurate.

Later in the draft Exposure Assessment, EPA suggests that the analyses using an absorption value of 100% were conducted because of concerns with the Casteel study. Specifically, p. 80 of the exposure assessment states: "Because the ACC pig study for bioavailability (ACC 2003c) involved feeding pigs residues mixed with feed, we conducted a simulation assuming 100%/day GI absorption rate for As residues (rather than beta(4.7,12.5) with mean 0.27)."

This statement mischaracterizes the ACC study because it implies that pigs were dosed with residues as part of their daily diet. Instead, pigs were fed residues contained in a small amount of moistened feed (*i.e.*, an approximately 5 gram dough ball) 2 hours prior to being fed their normal meal and after a night of fasting. It should be noted that some children who are exposed to residues will likely have fairly full stomachs whereas others may have fairly empty stomachs. Because children are fed *ad libitum*, completely empty stomachs during outdoor play periods are unlikely for most children. Thus, a pig with a small amount of feed in the stomach at the time of dosing represents a reasonable model for the average child.

2.7 Comparison with Results from Other Risk Assessments

The draft Exposure Assessment acknowledges that no applicable biomonitoring or other relevant exposure data are currently available to assess the validity of the model predictions. Instead, as an initial approach for assessing the plausibility of the SHEDS-Wood model results, EPA compares the results obtained from several previous assessments of children's potential exposures to structures built of CCA-treated wood. The assessments used in this comparison are summarized in Table 53 of the draft Exposure assessment (CDHS, 1987; CPSC, 2003b; Gradient 2001; EWG, 2001; Exponent, 2001; and Roberts and Ochoa, 2001). As described below, the assessments included in this comparison are not all directly comparable due to differences in approaches or concerns regarding the technical adequacy of certain elements of the approaches. Moreover, in the specific comparison of EPA's results with the results from the Gradient 2001 risk assessment, EPA provides a misleading perspective regarding the degree to which the results of the two analyses are similar, suggesting that the exposure estimates derived in the two analyses generally are within approximately a factor of 2. A detailed comparison of the exposure estimates derived from the EPA and Gradient analyses demonstrates that the EPA estimates for some of the evaluated scenarios are more than twenty-fold greater than the estimates derived in Gradient evaluations of similar scenarios.

The draft Exposure Assessment presents the assessments used in the comparison as if all are equally valid and directly comparable. In fact, these assessments differ substantially in numerous ways including the scope and goals of the assessments, the modeling approaches used, and the underlying data applied in the calculations. As a result, direct comparisons of the results of these analyses are not always appropriate. For example, the CDHS analysis is considerably older than the others, and was prepared at a time when the available data resources were quite different. The assessments also differ in the source of metals loading data on wood surfaces that were used, with some assessments applying data collected using a wipe method and others applying data collected using a hand loading method. Approaches used to model the transfer of residues from wood surfaces to hands, and subsequently into the mouth, also vary among the assessments; with most assessments using an empirical hand transfer efficiency, and others using a mechanistic approach like that applied by EPA in the SHEDS-Wood model. The assumed exposure frequencies also vary among the assessments. In general, as can be seen in Table 52 of the draft Exposure Assessment, the variables used for the various exposure factors vary greatly among the different assessments and complicate direct comparisons among them.

In addition to the differences in approaches among the assessments, it should be noted that the assessment prepared by the Environmental Working Group (EWG) contains several significant flaws. For example, to determine arsenic residue concentrations for use in the assessment, EWG used a study by Riedel et al. (1980). EWG appears to have misinterpreted this study, however, resulting in overestimates of exposures related to dislodgeable residue. Other studies used by EWG in its analyses varied widely in their methods, leading to the development of erroneous input distributions in the EWG assessment. The EWG model also used outdated analyses of soil ingestion and combined distributions for some input parameters and with highly conservative or worst-case point estimates for other parameters, resulting in biased distributions of potential exposures.

In its comparison of the results of the draft Exposure Assessment with results from Gradient's 2001 human health risk assessment, EPA states that "The SHEDS-Wood variability results (bounding estimates for warm and cold climates), based on inputs and algorithms developed independently of the other models, are within a factor of 2 for the Gradient (2001) results for all pathways and aggregate dose." While EPA doesn't explicitly show how it derived this factor of 2 difference, the data used in the comparison appear to be that presented in Table 53 of the draft Exposure Assessment (as summarized in Table 2-2 below). The Gradient (2001) exposure estimates included in EPA Table 53 are those associated with residential exposures to CCA-treated wood and public playsets. The EPA exposure estimates included in EPA Table 53 are described as those associated children's exposures CCA-treated wood playsets in public playgrounds.

The Gradient estimates listed in EPA Table 53 reflect high-end exposure estimates presented in Gradient's analyses. These values were derived using residue data observed in treated southern yellow pine with applied water repellent, a type of treated wood that constitutes only a small fraction of the overall use of CCA-treated wood (6%; RISI, 1990). By contrast, the comparison exposure estimates extracted from the EPA analyses represent a subset of the total exposures examined in EPA's analyses.[1] This combination of high-end estimates from the Gradient analyses and lower-end estimates from the EPA analyses minimizes the differences between the two assessments. Moreover, as can be seen in Table 2-2, although the ratios for the residue ingestion pathway and the total exposures are in the 2-3 range (when the EPA estimates are compared with the maximum Gradient estimates for residential and playground exposures combined), some of the ratios for other individual exposure pathways or for other scenario comparisons are substantially greater than a factor of two. For example, when the EPA estimates are compared with the Gradient playground estimates, the EPA total exposure estimates are approximately a factor of 8 greater than the Gradient values, while ratios for individual pathways span more than two orders of magnitude. Such ratios suggest some significant differences in underlying assumptions for some of the individual exposure pathways and scenarios.

[1] It should be noted that the SHEDS-Wood exposure estimates presented in EPA Table 53 are inconsistent with the data presented in other portions of the draft Exposure Assessment. Specifically, the SHEDS-Wood/CCA column in Table 53 is footnoted with the remark "EPA results are for public playsets only." However, the average daily doses (ADDs) presented in this table do not correspond to those presented in any other tables in the document, including on EPA Table 30, which is the table presenting estimates for exposures to public playsets only. The lifetime average daily doses (LADDs) in Table 53 are found in EPA Table 14, but are located in the section reporting exposure estimates for home playsets for children with decks. Also, the aggregate numbers in this column do not match the numbers obtained from adding together the various exposure pathways. In general, the data tables in the draft Exposure Assessment would benefit from greater clarity regarding which information is being presented in which location, particularly when distinguishing between exposures to public vs. private playsets. In addition, Table 53 does not indicate whether the SHEDS-Wood ADDs presented are for short-term or intermediate-term arsenic exposure.

Table 2-2

Comparison of EPA and Gradient Exposure Estimates from EPA Table 53

	EPA [2]	Gradient 2001 Residential (high-end)[3]	Gradient 2001 Playground (high-end)[3]	Gradient 2001 Total (high-end)	Ratios EPA/Residential (high-end)	EPA/playground (high-end)	EPA/ 2001 total
Non-cancer							
Total	2.6E-04	6.6E-05	3.2E-05	9.8E-05	3.8	8.0	2.6
Total Residue Ingestion	1.5E-04	4.7E-05	2.7E-05	7.4E-05	3.1	5.3	2.0
Total Soil Ingestion	4.2E-05	5.3E-06	8.9E-07	6.2E-06	7.9	47.4	6.8
Total Dermal Residue Absorption	7.2E-05	1.3E-05	3.3E-06	1.6E-05	5.7	22.2	4.6
Total Dermal Soil Absorption	5.6E-05	1.9E-06	3.1E-07	2.2E-06	30.2	180.2	25.8
Cancer							
Total	1.8E-05	4.7E-06	2.3E-06	7.0E-06	3.8	8.0	2.6
Total Residue Ingestion	1.2E-05	3.3E-06	2.0E-06	5.3E-06	3.7	6.3	2.3
Total Soil Ingestion	2.8E-06	3.8E-07	6.4E-08	4.4E-07	7.4	44.4	6.4
Total Dermal Residue Absorption	6.0E-06	9.0E-07	2.3E-07	1.1E-06	6.7	26.0	5.3
Total Dermal Soil Absorption	3.9E-07	1.3E-07	2.2E-08	1.6E-07	3.0	17.5	2.5

Additional comparisons indicate greater disparities between the EPA and Gradient analyses. It should be noted that the Gradient 2001 assessment was prepared before additional CCA-specific studies were conducted to develop supplemental data for critical input parameters (*e.g.*, for bioavailability and residue concentrations). Because the EPA draft Exposure Assessment reflects consideration of these data, assessing the EPA results relative to results from an updated version of the Gradient analyses (Dubé *et al*., 2003) also provides a more sound comparison.

Table 2-3 below compares EPA exposure estimates with Gradient estimates derived using residue data for the most common type of CCA-treated wood (*i.e.*, treated southern pine). Because this type of CCA-treated wood accounts for 86% of the treated lumber sold in the U.S. (AWPA, 1998), exposure estimates derived using these data are more representative of potential U.S. exposures. In Table 2-3, EPA estimates (based on the warm climate scenario) for total public and residential playset exposure as well as deck exposure are compared with Gradient estimates for total residential and public playground exposures. The table lists both the high-end and more typical Gradient 2001 exposure estimates (reflecting exposures to both wood types discussed above, *i.e.*, treated yellow pine with and without water

[2] EPA 95th percentile exposure estimates from EPA Table 53, for children 1-6 years of age.
[3] Gradient reasonable maximum exposure (RME) case estimates from EPA Table 53, for children 2-6 years of age.

repellent). The table also includes updated exposures estimates from the Gradient 2003 analyses. These more recent estimates present the most appropriate values for comparing with EPA's estimates.

As can be seen in this table, when the combined exposure estimates for residential and playground exposures are compared, the Gradient and EPA total exposure estimates differ by almost an order of magnitude with some pathways diverging by almost three orders of magnitude.

Table 2-3

Comparison of EPA and Gradient 2001/2003 Exposure Estimates for Total Residential and Playset Exposures

					Ratios		
	EPA[4]	Gradient 2001-high-end[5]	Gradient 2001-typical[5]	Gradient 2003[6]	EPA/2001 high-end	EPA/2001 typical	EPA/2003
Non-cancer							
Total Exposure	4.7E-04	9.8E-05	5.1E-05	5.7E-05	4.8	9.3	8.2
Total Residue Ingestion	3.4E-04	7.4E-05	3.5E-05	2.4E-05	4.6	9.8	14.3
Total Soil Ingestion	3.5E-05	6.3E-06	6.3E-06	1.8E-05	5.5	5.5	1.9
Total Dermal Residue Absorption	1.5E-04	1.6E-05	7.5E-06	2.1E-07	9.7	20.5	714.3
Total Dermal Soil Absorption	8.0E-06	2.2E-06	2.2E-06	1.5E-05	3.7	3.7	0.5
Cancer							
Total Exposure	3.9E-05	7.0E-06	3.6E-06	4.1E-06	5.6	10.8	9.6
Total Residue Ingestion	2.5E-05	5.3E-06	2.5E-06	1.7E-06	4.7	10.1	14.7
Total Soil Ingestion	3.2E-06	4.5E-07	4.5E-07	1.3E-06	7.0	7.0	2.4
Total Dermal Residue Absorption	1.4E-05	1.1E-06	5.3E-07	1.5E-08	12.4	26.3	915.6
Total Dermal Soil Absorption	4.6E-07	1.6E-07	1.6E-07	1.1E-06	3.0	3.0	0.4

When the EPA and Gradient exposure estimates for public playground exposures are compared, even more divergent results are observed. As shown in Table 2-4, the ratios between the EPA and Gradient estimates for total public playset exposures range from approximately 10 to 25. Again, ratios for certain specific pathways are even greater.

[4] EPA 95th percentile exposure estimates from EPA Tables 14 and 18, assuming warm climate scenario and short-term exposure for ADDs; assuming warm climate for LADDs; for children 1-6 years of age.
[5] Gradient RME case estimates from Gradient (2001), for children 2-6 years of age. Estimates presented in Gradient (2001) worksheets E-11, E-14, E-16, E-19, E-42, E-43, E-44, E-45, E-46, E-53, E-54, E-55, E-56, and E-57.

[6] Gradient RME case estimates from Dubé *et al*. (2003), Worksheets 1, 4, 6, 9, 11, 14, 16, and 19; for children 2-6 years of age.

Table 2-4

Comparison of EPA and Gradient Exposure Estimates for Public Playgrounds

	EPA [7]	Gradient 2001 (typical)[8]	Gradient 2001 (high-end)[8]	Gradient 2003 (playground)[9]	**Ratios** EPA/Gradient 2001 typical	EPA/Gradient 2001 high-end	EPA/Gradient 2003
Non-cancer							
Total Exposure	3.1E-04	1.6E -05	3.2E-05	1.2E-05	20.0	9.8	26.7
Total Residue Ingestion	1.9E-04	1.3E-05	2.7E-05	7.0E-06	14.8	7.0	27.2
Total Soil Ingestion	4.3E-05	8.9E-07	8.9E-07	1.9E-06	48.5	48.5	22.3
Total Dermal Residue Absorption	8.4E-05	1.5E-06	3.3E-06	9.1E-08	54.9	25.9	921.1
Total Dermal Soil Absorption	6.6E-06	3.1E-07	3.1E-07	2.5E-06	21.0	21.0	2.6
Cancer							
Total Exposure	1.8E-05	1.1E-06	2.3E-06	8.3E-07	16.2	7.9	21.7
Total Residue Ingestion	1.1E-05	9.2E-07	2.0E-06	5.0E-07	12.0	5.6	22.0
Total Soil Ingestion	2.3E-06	6.3E-08	6.3E-08	1.4E-07	36.3	36.3	16.7
Total Dermal Residue Absorption	5.5E-06	1.1E-07	2.3E-07	6.5E-09	50.5	23.7	843.6
Total Dermal Soil Absorption	4.3E-07	2.2E-08	2.2E-08	1.9E-07	19.3	19.3	2.3

Thus, in contrast with the statements made in the draft Exposure Assessment, the results of the EPA analyses diverge quite substantially from those presented in the Gradient analyses.

On p. 155 of the draft Exposure Assessment, EPA comments, "Ideally, SHEDS-Wood dose estimates could be compared against real-world biomonitoring data for the modeled population of children who contact CCA-treated playsets and deck. Unfortunately, no such data for the target population currently exist. Thus, model evaluation in this section focuses primarily on model-to-model comparison, i.e., comparing SHEDS-Wood equations, inputs and outputs against other CCA models." The draft Exposure Assessment also states that "The inter-model comparison was especially important because the SHEDS-Wood CCA results were found to be consistent with estimates of other models, whose algorithms and inputs were derived independently." In fact, as demonstrated in these comments, in many cases, the assessments cannot be directly compared because of differences among the assessments in the approaches used, the input data, and the validity of the results produced. Moreover, as illustrated

[7] EPA 95th percentile data obtained from Table 30, for children 1-6 years of age, assuming warm climate and short term exposure for the ADDs and warm climate for the LADDs.

[8] Gradient RME case estimates from Gradient 2001, for children 2-6 years of age. Estimates provided in worksheets E-11, E-14, E-16, E-19, E-42, E-43, E-44, E-45, E-46, E-53, E-54, E-55, E-56, and E-57 .

[9] Gradient RME case estimates obtained from Dubé *et al*. (2003), Worksheets 4, 9, 14, and 19; for children 2-6 years of age.

by the assessment of EPA's comparison with the results of the Gradient exposure analyses, numerical inaccuracies exist in EPA's presentation and interpretation of the comparisons. This observation calls into question EPA's support for the results of the SHEDS-Wood modeling based on their comparability with the results of previous analyses, and underscores the need to collect biomonitoring or other relevant exposure to assess the validity of the SHEDS-Wood model predictions.

3 Comments on Other Assessment Components

3.1 Model Scenarios

3.1.1 Population Definition

In the initial description of the population focused on in the assessment (p. 16), EPA provides a qualitative description of the population of interest for this exposure assessment, *i.e.*, children who might frequently encounter public playsets built of CCA-treated wood at a playground, school, or daycare center. Children who might also encounter other structures built of CCA-treated wood in a residential setting (*i.e.*, decks or playsets) were also considered.

Quantitative information regarding the magnitude of this population is provided in various locations throughout the draft Exposure Assessment. For example, in the *Background* section (p. 7), EPA provides estimates of the percentage of U.S. single-family homes that have decks or porches constructed of some type of treated wood and the percentage of public playground equipment that may be constructed of some type of treated wood. In the section describing *SHEDS-Wood Inputs for CCA Study* (pp. 65 and 67), EPA describes the basis for its assumptions regarding the fraction of children who have a CCA-treated home playset (8%) or deck (50%) – two input parameters that were used in the exposure modeling.

In both cases, no specific data were available regarding the use of CCA-treated wood in such structures. Instead, by using data reflecting the use of any type of treated wood, EPA inherently assumed that such data could serve as a surrogate for estimating the use of CCA-treated wood. While CCA-treated wood has historically been the predominant form of treated wood used in decks and playsets, this assumption still reflects a conservative assumption that is likely to overestimate actual exposures to CCA-treated structures. EPA should more clearly acknowledge the conservatism of this approach in its documentation of these parameters.

In addition to using data for all treated wood structures to estimate input parameters for structures built of CCA-treated wood, EPA's estimates for these two variables reflect other elements of professional judgment. In particular, EPA's estimate of the percentage of children who live in non-single family homes who may have a CCA-treated deck (10%) is based solely on professional judgment. This assumption plays a role in EPA's overall estimate of the fraction of children who have a CCA-treated residential deck. In the summary table of input parameters (Table 12), the basis for this parameter is misleadingly listed as a study (Shook and Eastin, 1996) and U.S Census data (2000). The role of professional judgment in this parameter should also be indicated on this table. In addition, the entries for both this parameter and the fraction of children with a CCA-treated home playset should reflect the fact that the underlying data relied upon in deriving these input parameters represents information for all treated wood, not just CCA-treated wood. As discussed in more detail above, such an approach will provide a more accurate perspective on the role of professional judgment in the model assumptions and the uncertainties inherent in the model.

The draft Exposure Assessment should also include some discussion of the potential magnitude of the exposed population of interest in several other locations in the document. In particular, based on data from a survey of 1,037 public playgrounds, EPA's documentation indicates that only 14% of public playgrounds contain some type of treated wood (CFA and USPIRG, 2002). Thus, the exposure estimates generated in the draft Exposure Assessment do not apply to the entire U.S. population, but only to a segment of the population. Moreover, because of the nature of the "warm" and "cold" scenarios that EPA applied in its analyses, the resulting exposures are not reflective of a particular population, but instead represent "bounding" estimates of possible exposures. This information should be reflected in the Executive Summary of the document as well as in the discussion of the model results, to provide context for the calculated risk estimates. These factors should also be considered when interpreting the assessment results (particularly when considering the likely size of the population of interest) and considering appropriate population percentiles for assessing the significance of the calculated exposures.

3.1.2 Exposure Pathways

The discussion of the exposure pathways included in the draft Exposure Assessment notes that the analyses excluded certain potential, but less common exposure pathways from the exposure calculations. These pathways include potential exposures *via* affected soil or residue that have been tracked into homes. As recognized by EPA, because the area of soil potentially affected by structures built of CCA-treated wood is limited, *i.e.*, to the area within approximately 2 ft of the structure, this soil is unlikely to represent a significant source of material for transport into homes. Similarly, the mass of residue available for transport is also limited. As a result, EPA has correctly concluded that these exposure pathways are likely to be negligible contributors to any indoor exposures.

3.2 Other Exposure Model Inputs

- *Background Information* (p. 6) – The exposure assessment correctly recognizes that chromium VI is not a concern for assessing potential exposures and risks associated with CCA-treated wood. As noted in the exposure assessment, chromium VI has not been detected in existing residue studies (ACC, 2003a).
- *Summary of parameter distributions* (pp. 58-64) – To provide some perspective on the types of more extreme parameter values contained within the parameter distributions, it would be helpful to expand this table to include summary statistics corresponding to higher and lower percentiles than are presented in this table (*e.g.*, p5, p95, p99).
- *Body weight distribution* (p. 58) – The distribution for body weight is not included in Table 12.

3.3 Sensitivity and Uncertainty Analyses

The draft Exposure Assessment presents sensitivity and uncertainty analyses that were conducted as part of the modeling process. Based on the methodologies used, the sensitivity analyses indicated that the most critical input variables influencing variability in the model are the wood surface residue-to-skin transfer efficiency, the wood surface residue on CCA-treated decks, the fraction of the hand surface that is mouthed per mouthing event, and the number of hand washing events per day. The first three of these were also identified as important parameters in the uncertainty analyses. In addition, the wood surface residues on CCA-treated playsets and the gastrointestinal daily absorption fraction for residues were also identified as important factors in assessing the uncertainties inherent in the model.

Strikingly, the uncertainty analyses did not identify any of the factors associated with the frequency of children's exposures to CCA-treated wood structures as important variables influencing model uncertainties. As acknowledged by EPA (p. 3), limited data are available regarding such factors as the number of days per year that a child may play around a CCA-treated wood deck or playset or the fraction of time that a child actually contacts treated wood during play. In most cases, these factors influencing contacts with structures built of CCA-treated wood were not based on direct information regarding children's contacts with CCA-treated structures. By contrast, factors such as the residue-skin transfer efficiencies and arsenic and chromium in wood surface residues were based on directly relevant data. Instead, the parameters associated with exposure frequency were typically based on other types of data which EPA then assumed could be directly applied to estimate the actual parameter of interest. As discussed below, it is counter-intuitive that parameters based on a synthesis of multiple, sometimes indirectly relevant studies should be represented as less uncertain than parameters based on studies specifically designed to measure those parameters.

For example, the fraction of outdoor time that a child is assumed to spend playing on or around a CCA-treated playset or deck (on a day that such activities occur) is based on data regarding the proportion of total outdoor time that a child spends at a playground on a day when a playground visit occurs. Thus, a critical component of the uncertainty in this factor is not the numerical uncertainty reflected in the selected distribution, but uncertainty regarding whether the selected distribution is in fact applicable for the actual parameter of interest. Similarly, some of the input distributions for these factors are based on short-term measurements (*e.g.*, activity data from the CHAD database), but are used to predict long-term exposure conditions. Thus, as recognized by EPA, temporal uncertainties also play a role in these parameter estimates.

Because values for these factors can vary widely and can play a significant role in determining exposures to CCA-treated wood, it is important that uncertainties associated with these variables be appropriately characterized. Based on an initial review, it appears that the failure of EPA's uncertainty analysis to identify factors such as those associated with children's frequency of exposure to CCA-treated structures as being important is related more to the methodology used in the uncertainty analysis than to the uncertainties inherent in the factors. In particular, although the documentation of the uncertainty analyses is sparse, EPA appears to have used techniques such as bootstrapping analyses to explore the degree of uncertainty inherent in the specific distributions selected in the analyses. EPA does not appear to systematically explore, however, uncertainties inherent in the original choices for the variability distributions.

EPA should expand its uncertainty analyses to include a broader perspective on the sources of uncertainty in the analyses. As presently described, several key parameters are represented with greater certainty than is warranted and, in some cases (*e.g.*, hand-to-mouth contact frequency) may be biased high. EPA should also provide better synthesis and interpretation of the significance of the uncertainty analysis results. In addition, EPA should enhance the documentation provided for the uncertainty analyses to better justify the choices made in the evaluations (*e.g.*, the number of model runs included in the analyses) and to clarify some of the terminology used to describe the analyses.

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