

October 17, 2005

Information Quality Guidelines Staff US EPA - Room M1200 1300 Pennsylvania Ave., NW Washington, DC 20008

Re: Information Quality Act Request for Correction

Dear Sir or Madam:

This request for the correction of information is submitted on behalf of the Wood Preservative Science Council (WPSC), under the Information Quality Act (IQA)¹ and the implementing guidelines issued, respectively, by the Office of Management and Budget (OMB)² and the U.S. Environmental Protection Agency (EPA).³

The WPSC is a trade association of manufacturers of water borne wood preservatives, including chromated copper arsenate (CCA). It supports and participates in objective scientific analysis of water borne wood preservatives with a focus on CCA. The WPSC is supported by its members, Arch Wood Protection, Inc., Chemical Specialties Inc., and Osmose Inc. The WPSC consults with the nation's leading experts in the fields of environmental science, epidemiology, risk assessment, and toxicology.

EPA's Guidelines expressly contemplate the correction of information disseminated by EPA that falls short of the "basic standard of quality, including objectivity, utility, and integrity," enunciated in its own Guidelines or those issued by OMB.

Pursuant to those guidelines, the WPSC seeks the correction of the following document:

Evaluation of the effectiveness of coatings in reducing dislodgeable arsenic, chromium, and copper from CCA treated wood. Interim Data Report. EPA/600/R-05/050, 5/9/2005" (EPA Report or the report).

¹ Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, P.L. 106-554; 44 U.S.C. § 3516 (notes).

² 67 Fed. Reg. 8452 (Feb. 22, 2002).

³ EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008 (Oct. 2002).

The WPSC believes that there are serious deficiencies in the report that need to be corrected. The report is influential information under EPA's data quality guidelines, as the data obtained from this study will be used by EPA in regulatory decision-making and to advise the public regarding the use and maintenance of existing CCA-treated wood products, such as decks and playground equipment. In addition, the report is also influential with regard to state and local regulatory decision-making, as many states and localities may look to EPA for guidance with regard to regulations on coating treated wood structures. Thus, the dissemination of the report has "a clear and substantial impact [] on important public policies or private sector decisions." EPA Guidelines at 19. Moreover, the report has clearly been "disseminated," as it is available on EPA's website.⁴ As such, the WPSC believes that EPA must consider the potential issues associated with the report as it now stands and correct the interim report as well as take the issues into account in the final report.

The EPA Guidelines provide that, in the dissemination of "influential scientific information regarding human health, safety, or environmental risk assessments," EPA will ensure the objectivity of such information by adapting the principles found in the Safe Drinking Water Act Amendments of 1996. Specifically, EPA's principles require that "the substance of the information is accurate, reliable, and unbiased," which "involves the use of the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies...." EPA Guidelines at 22 (emphasis added). The interim coatings report fails to meet these standards.

We believe that the deficiencies in the report fall into one of two main areas: 1) errors in the design and conduct of the study, and 2) errors in sampling and interpretation of the data. In both areas, the Agency needs to consider whether a bias has entered into the conduct and report of the scientific investigation. One of the most notable deficiencies is the report's failure to explain results that are inconsistent with the findings presented. For example, EPA's interpretation of the results is that the coatings were generally effective in reducing arsenic residues. However, "coating 13," which is a positive control without any coating, also reduced residues of arsenic by nearly 70% at the 1-month sample compared to the baseline value. Thus, a possible interpretation is that simple cleaning of decks might also be a valid approach to reducing metal residues, rather than applying a coating. No explanation for this result is provided in the report, however, even though it directly contradicts the Agency's interpretation of the data.

I. Issues with the Study Design

There are several study design issues concerning the deck materials, sampling methods, coating selection and design assumption. It should be noted that the EPA report identified a number of limitations in section 2.1.3. However, none of these limitations were considered in the data analysis or discussed in the interpretations and conclusion sections of the report.

A. Deck materials

⁴ http://www.epa.gov/oppad001/reregistration/cca/sealant_study.pdf

The length of the boards was 34" (page 25, figure 2-6 schematic of minideck construction), which is substantially below the minimum 8 ft length identified by the industry and knowledgeable experts to account for issues associated with stress on the boards.

There were only 2 sources of wood, both of which were supposedly of a similar type (Southern yellow pine). One was from an institutional site in Research Triangle Park (RTP), approximately 7 years old, and was believed to have received one application of a standard deck sealant near the beginning of its use (over 5 years ago). The other was from a private residence in "New Hill" - also in North Carolina near RTP. That deck was approximately 1 year old and had never been cleaned or treated. There was no information on when the wood actually was treated; only estimates of how long the actual decks had been in place. Further, there is no information as to why the two sources were used in the study. Since both source woods came from the existing decks in the same geographical area and the study was conducted at one location in North Carolina, the study design did not take into account potential geographical variation.

B. Sampling issues

Baseline measurements were taken before the wood surfaces were rinsed (page 24). This is likely to result in high baseline levels and differences of post-treatment versus baseline may not be solely due to "coating efficacy." Thus, using these baseline values for purpose of comparison of the effectiveness of the various coatings could lead to erroneous conclusions.

Page 14 of the report noted that baseline samples were taken using wipes that had been washed in nitric acid to remove any trace contaminants. It was later determined that DI water rinsing was not sufficient in removing nitric acid. Subsequent sampling was done with "out of the bag" wipes, simply wetted with DI water. This change in sampling requires adjustment of base line measurements in subsequent data analysis. This additional adjustment to the baseline measurements due to the changes in sampling method resulted in additional uncertainties about coating efficiencies when baseline values are the basis for efficacy determination.

Moisture content of the wipes was identified as having a large effect on the level of dislodgeable residues (see pg 41). However, the effect is not adequately described nor is there any clear explanation of how such differences were controlled, outside of a general effort to avoid wiping surfaces during rain.

Page 50 of the report indicated that the sampling apparatus does not always appear to apply even wipe sampling pressure during sampling, particularly if the wood member is even slightly deformed, warped or cupped. Also, the average "speed" of wipe sampling may vary depending on the roughness of the surface being sampled. The impact of this heterogeneity on wipe measurements is unknown and not further evaluated in the study.

The number of replications was much too low to account for the extensive variability inherent in wood and coatings and for the number of factors being considered.

C. Coating selection and preparation

The selection of coatings was based primarily on convenience of purchase. The report noted that a thorough review of available coatings and their formulations and application techniques is needed to

more completely understand the characteristics that may impact DA (page 29). It seems this review should have preceded the conduct of a costly study such as the one presented in this report. Coatings vary tremendously in their formulation, yet because only limited information is available on the tested coatings, it is not possible to determine whether those tested are representative of that particular type of coating. Further, at least 5 of the tested coatings are unlikely to be available after 2006 due to requirements related to volatile organic compounds under the Clean Air Act. This limitation has not been addressed and may be misleading to consumers and others reading the report in terms of product availability. Reformulated products to address the VOC issue likely will not have the same characteristics as the tested products. We also believe the study may not reflect the true performance of the tested coatings, since normal abrasion due to use of the wood was not considered.

D. Study assumption

The design of the study is based on the assumption that smaller variation is expected within board than between boards (p. 13). Further analysis (p. 80) indicates that intraboard variability can be large (> 50% RSD), particularly with the board that came from the older deck source (source A). As such this assumption is not valid. However, no analysis of the importance of this deviation from the baseline assumption is presented.

II. Issues with Data Analysis Methods and Results

A. Methods

The approach described under method (4) (p. 56 & 57) does not seem to account for the fact that the various measurements taken over time could be correlated. While the report described method 4 as being a "more rigorous' method than the other approaches used to compare coatings (p. 131), this method may not be the most appropriate approach, as it does not take into consideration the repeated measures design.

One of the methods used to analyze the data is an "analysis of variance mixed model, similar to a split plot model in space and time" (p. 109). This method is not appropriate for the data generated by this study, as it does not take into consideration the fact that the multiple measurements taken across time from the same deck are potentially correlated. Repeated measures analysis of variance techniques should have been used.

B. Core Samples

The report identifies that the core wood samples were taken from the wide face of the board. Overall there are large differences in metal levels measured in core samples. Core samples from source A have an average arsenic level of 1645.4 mg/kg with RSD of 47.9% and individual values ranging from 28 to 3445 mg/kg. Samples from source C have an overall average arsenic level of 2074.2 mg/kg with RSD of 48.9%, with individual values ranging from 64 to 4624 mg/kg. (See Tables 4-3 and 4-4, p.68-77 of the report). The large differences in metal levels measured in the core samples suggest that that there is variability in baseline levels.

C. Baseline Samples

Similar to the core sampling data, the baseline wipe sampling data as reported in tables 4-6 and 4-7 show large variability. Baseline wipe samples from source A showed overall average arsenic level of 1.81 μ g/cm2, RSD 43.4%, with individual values ranging from 0.38 to 5.85 μ g/cm2. Baseline samples from source C has an overall average arsenic level of 1.00 μ g/cm2, RSD 51.7%, with individual values ranging from 0.28 to 3.05 μ g/cm2. Given this large variability in the baseline data, it is not clear how much of the variability between coatings is due to differences in baseline values. Specifically, coatings used on decks with lower baseline values may appear less effective than coatings used on decks with higher baseline values.

Baseline reference values were determined by averaging the results of wipe samples from areas adjacent to the sampling areas. (p.5, p12, p41). This approach effectively reduces the observed large variability in the baseline comparison levels and could potentially lead to an overestimation of the significance of the differences.

We note that data from the same sections of the boards were used in the calculation of average baseline values for different primary sampling areas (PSA) (p. 22, figure 2.5 on p. 23). Therefore, the baseline comparison values may not be independent. The analysis does not take that lack of independence in consideration, and the impact of this lack of independence on study results is not presented.

Wipe method correction factors were used to convert the baseline wipe sample results taken using acid washed wipes (the A2 method) to the 2X method (as used in subsequent sampling events) (p.59). The correction factors were derived based on calibration equations developed from a separate wipe comparison study. Limited information from the calibration study was provided in the report. The detail of the calibration study was in a separate appendix and not reviewed. Nevertheless, the adjustment of the baseline concentrations adds another level of uncertainty to the study results.

D. Coatings

It is noted that there are relatively large variations in amounts of coating applied to the three replicate decks (per coating) (p. 65, figure 4.1, p. 67). However, no adjustment was made for this variability in the subsequent data analysis. What implication this might have on the study results is unknown.

E. Dislodgeable metals, reduction and efficacy

In general, formal statistical analyses are not presented with graphs and summary tables shown in the report. For example:

- Graphs relating levels measured to distance between the areas from which these measurements were taken on a given board are presented. However no formal statistical analysis is presented, and a general statement about lack of correlation is presented (p. 96). In addition, the figures on p. 97 and 98 appear to contradict this statement.
- Graphs relating levels measured in core samples and background levels are presented. A general statement about the correlation between these measurements

is presented (p. 103), but no formal statistical analysis is presented. In addition, the figures (p. 103 & 104) present the results of the three analytes on the same graphs. It is not clear whether the reported "apparent correlation" is due to differences in levels between the three analytes or to actual correlations.

- Tables of mean dislodgeable metal levels are presented without estimates of variability (e.g., standard deviations, standard errors or confidence intervals) (Tables 4-10, 4-11 and 4-12, p. 108 & p. 111). It is thus not possible to determine whether the difference in the levels is statistically significant.
- Average reductions in concentrations are presented in several data tables (p. 117 to 130). Neither estimates of variation nor results of formal statistical tests are presented.
- Summary tables comparing the efficacy of the various coatings are presented, in which coatings are ranked by their efficacy (p. 134 to p.140). No estimates of standard errors are shown. It is thus not possible to determine whether the apparent differences between the coatings are statistically significant.

Tables of mean levels are presented for the measurements taken at the various time intervals (111-113). Given these results, the EPA report concluded that there is a reduction in residue levels at 1-month post treatment as compared to baseline values and that levels increase with time after treatment. This increase is interpreted as an indication of the effect of weathering. However, levels appeared to continue to decline until three months post treatment. Also, "coating 13," which is a positive control without any coating, actually had reduced residues of arsenic by nearly 70% at the 1-month sample compared to the baseline value (p.111). A possible interpretation is that simple cleaning of decks might also be a valid approach to reducing metal residues. No explanation for these facts, which contradict EPA's interpretation, is provided.

III. Peer-Review

Both EPA and OMB have stressed the importance of peer review for scientific documents.⁵ However, the report has not been peer-reviewed, and there is no indication the Agency intends to submit it for peer review in the future. Peer review of this document could help address the serious scientific issues addressed above, such as ensuring that the data is properly interpreted. In the interim, EPA should make clear in the report and on the website that this is an interim draft that has not been peer-reviewed, does not represent an Agency position, and should not be cited or relied upon.

IV. Conclusion

The WPSC appreciates the Agency's prompt attention to our concerns regarding the report. As outlined above, there are serious issues concerning the study design, sampling, and data analysis that must be corrected. In addition, the Agency should make clear that the study is only a pilot study,

⁵ EPA Guidelines at 11.

conducted in a single geographical region, using 2 sources of wood, and that therefore the results are not representative of all woods and geographical locations. We also urge the Agency to ensure the document will be subject to formal, external peer review, which could help address the serious scientific issues with the document addressed above.

Thank you for your consideration of this request.

Respectfully submitted. James Hale