

U.S. CONSUMER PRODUCT SAFETY COMMISSION WASHINGTON, DC 20207

OFFICE OF THE GENERAL COUNSEL

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December 28, 2005

Mr. James Hale
The Wood Preservative Science Council
P.O. Box 293
Mount Vernon, VA 22121

Dear Mr. Hale:

The following is in response to your letter of October 17, 2005 to the Office of the Secretary concerning the Consumer Product Safety Commission staff report entitled Evaluation of the Effectiveness of Surface Coatings in Reducing Dislodgeable Arsenic from New Wood Pressure Treated with Chromated Copper Arsenate (CCA) (the Report), May 2005. It is the position of the General Counsel that the Report is not eligible for the Administrative Correction Mechanism of Commission's Information Quality Guidelines,

http://www.cpsc.gov/library/infoguidelines.html, because the report has not been "disseminated" by the Commission as that term is defined by the Office of Management and Budget (OMB).

The Report bears a disclaimer on its cover stating that "these comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission." Thus, it has not been "disseminated" because the OMB definition of that term expressly "excludes research produced by government-funded scientists (e.g., those supported ... intramurally by Federal agencies ...) if that information does not represent the views of an agency." Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2674-5 (January 14, 2005).

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CPSC Hotline: 1-800-638-CPSC (2772) CPSC's Web Site: http://www.cpsc.gov



U.S. CONSUMER PRODUCT SAFETY COMMISSION WASHINGTON, DC 20207

Todd A. Ster Office of the Ser Tel: 301-504 E-Mail: tstevenson@cp:

November 4, 2005

Mr. James Hale Wood Preservative Science Council P.O. Box 293 Mount Vernon, VA 22121

Re: CCA Interim Report

Dear Mr. Hale:

This is to confirm receipt of your correspondence of October 17, 2005 concerning the Consumer Product Safety Commission staff report entitled Evaluation of the Effectiveness of Surface Coatings in Reducing Dislodgeable Arsenic from New Wood Pressure Treated with Chromated Copper Arsenate (CCA) (the Report), May 2005. We are evaluating your letter in accordance with the Commission's Information Quality Guidelines and will respond accordingly in due course.

Sincerely

Todd A. Stevenson

Secretary



October 17, 2005

Office of the Secretary
U.S. Consumer Product Safety Commission
Washington, D.C. 20207

Re: Information Quality Guidelines

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 by the Office of Management and Budget (OMB)² and the U.S. Consumer Product Safety Commission.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.

The CPSC's Guidelines expressly contemplate the correction of information that falls short of the "basic standard of quality, including objectivity, utility, and integrity," enunciated in its own Guidelines or those issued by OMB. With regard to objectivity the CPSC guidelines provide:

Objectivity involves a focus on ensuring that information is accurate, reliable, and unbiased and that information products are presented in an accurate, clear, complete, and unbiased manner. Objectivity is achieved by using reliable data sources and sound analytical techniques, by having information products prepared by qualified people using proven methods,

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 Office of Management Budget Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. Final Guidelines. 67 Fed. Reg. 8452 (Feb. 22, 2002).

³ Available at: http://www.cpsc.gov/library/infoguidelines.html.

and by carefully reviewing the content of all information products. Pursuant to the guidelines, the WPSC seeks the correction of the following document:

CPSC Interim Report: Evaluation of the effectiveness of surface coatings in reducing arsenic from new wood pressure-treated with chromated copper arsenate (CCA). May 2005. (CPSC Report or the report).

The WPSC believes that there are serious deficiencies in the report that need to be corrected. The report is influential information under CPSC's data quality guidelines, as the data obtained from these studies will be used by CPSC 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. Thus, the dissemination of the report has "a clear and substantial impact [] on important public policies or private sector decisions." OMB Guidelines at § V(9). Moreover, the report has clearly been "disseminated," as it is available on CPSC's website. As such, the WPSC believes that CPSC 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 interim coatings report fails to meet the OMB and CPSC standards of quality, including objectivity, and utility. 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.

I. Lack of Adequate Information

It appears that analysis of variance (ANOVA) methods were used to assess the impact on dislodgeable arsenic levels of coatings, sampling schedule, and which sections of the planks samples were taken from. However the results of that analysis are not presented in the document (either in the text or as an ANOVA table). Without adequate summary of the output information from this analysis, it is not possible to fully assess the validity of the conclusions that are based on this analysis provided in the CPSC report.

The number of observations (sample size) is not clearly presented. Thus, it is difficult to assess the adequacy of the sample size and its implications for study results and interpretation.

The conditions under which the baseline samples were taken are inadequately described. It is unclear as to how and when baseline samples were taken and potential impact on the results. The report describes, "only the west sections were wipe sampled prior to coating and serve as controls along with wipe samples from the closest end section, e.g. the control for plank A consists of its west section A1 and the end section AE, in figures 1 and 2 of the report." However, based on the same figures 1 and 2, it is difficult to determine which end section in plank B would be used as controls, presumably along with the sampling of the west section B1 before coating.

⁴ http://www.cpsc.gov/library/foia/foia05/os/ccamitig.pdf

The measured background (control) levels are not presented in the report. Therefore, it is not possible to determine if apparent differences in relative changes between decks reflect true differences in coating effectiveness or the fact that some decks may have had higher background levels to begin with, and hence would have been associated with apparently higher reductions.

II. Issues with the Study Design

Despite knowing that wood newly treated with CCA would no longer be available within a matter of months, CPSC used new wood in this study. Since newly treated wood is no longer available and since it is well established that new and aged wood respond very differently to coatings, the results of this study will not provide any meaningful information.

Page 16 of the report indicates, "32 CCA-treated boards from a single source were randomly allocated for the construction of the minidecks. The randomization had the restriction that no two planks from a single board were allocated to the same minideck, thus reducing the effect of the variability among boards in comparing results from different minidecks." However, this is not a random assignment, but rather a systematic one. Diagrams of minidecks that identified planks by source are needed to clarify how plank assignments were made.

Partway through the study, CPSC also added two additional minidecks, one of which was treated with different three coatings on different boards. The sources of wood for these two added decks were not described. Further, the sampling frequency was also different for one deck (page 16). Despite these changes, the results from these two added decks were analyzed with other minideck results as if they were the same. The reasons for the changes in study design were not explained.

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 the 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. Reformulated products to address the VOC issue likely will not have the same characteristics as the tested products. This limitation has not been addressed. We also believe that the true performance of the tested coatings has not been evaluated since normal abrasion due to use of the wood was not considered in the study. If normal use were considered, the performance of the coatings would likely be reduced.

III. Issues with Data Analysis

The document reports that a "regression model" was used (page 17). However, it is not clear how a categorical variable such as "coating" would have been used in the regression model. Was it included as a single variable, thus implying a linear association between the coating "number" and arsenic levels? Or was it included as a set of indicator (dummy variables)? It is most likely that an ANOVA was used, since results of post-hoc tests (Scheffe's confidence intervals) are presented (p. 21 & 22). The use of these post-hoc tests implies that the initial analysis resulted in a significant effect, however that ANOVA summary is not presented and should have been.

On page 17, the document states that "two outcome measures were used: (1) the amount of dislodgeable arsenic and (2) the percent of dislodgeable arsenic relative to the baseline dislodgeable arsenic." However, given that background levels were variable, the first measure (unadjusted amount of

dislodgeable arsenic) is not an appropriate measure as it would not be possible to determine if any differences observed between coatings are reflecting the differences in background (pre-coating) levels or actual coating effect differences.

Further, the report does not present the results of these analyses except to comment on page 20 that the "absolute amount results are a rescaling" of the relative percent results. The report also indicates that two scalars were used in the rescaling: 1) average of all baseline measurements (79.8 ug) and 2) conversion factor from wet-polyester surrogate to human hand (0.076). The use of the overall average of baseline measurement ignores the expected differences in the background levels and is therefore inappropriate. This scaling factor should have been different for the various decks. The basis for the conversion from the "wipe sample" to a human hand, e.g. assumptions of the size of the human hand, was not discussed.

The analysis is conducted in log-scale and then results are back-transformed. It is difficult to interpret the retransformed results. For example, in the original scale, the relative baseline adjusted dislodgeable arsenic (R) per plank is the measured dislodgeable arsenic (A) divided by the measured baseline arsenic (B), and the R per minideck is the average of R of all sampled planks on the minideck. In the log scale, R is based on the log transformation of the measurements (as indicated on page 18). The retransformation of the average R per minideck to original scale would provide estimates that are not the same as the average R per minideck calculated in the original scale. The interpretation of the retransformed average R per deck is thus difficult and may not be meaningful.

IV. Issues with Results Interpretation

The explanation presented on page 10 that the apparent increase in levels after one year after "constant reduction in arsenic release from CCA-treated boards after a year of natural weathering" may be due to "surface erosion and weathering" does not explain why the same pattern was observed in the non-CCA treated mini-deck. (Figure A9, page 30) This phenomenon is not adequately addressed in the report.

Page 19 of the report indicated, "the west section measurements differ from those from the east section in that they received a single sampling prior coatings." This suggests that the baseline adjusted dislodgeable arsenic for the east section is based on the baseline levels found in the west end of the planks, as such the validity of the results and conclusion of no difference between west and east section measurements (page 7 and figure 3) may be invalid if within plank variability is high (as is known to be the case).

In the calculation of baseline adjusted dislodgeable arsenic, the baseline amount used was the average of the west section and end section measurements taken prior to the application of the coatings for the plank (page 17). By using an average of two baseline values for comparison, the variability in background comparison levels is reduced and could potentially result in an overestimation of the significance of the difference.

V. The Report Has Not Been Peer-Reviewed

Both CPSC and OMB have stressed the importance of peer review for scientific documents. However, the report has not been peer-reviewed. Peer review of this document could help address the

serious scientific issues with the documents addressed above. Moreover, CPSC should make clear that the report is an preliminary draft based on interim results, and that the report has not been peer-reviewed, does not represent a Commission position, and should not be cited or relied upon.

VI. Conclusion

The WPSC appreciates the Commission'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. We also urge the Commission 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