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

OFFICE OF THE GENERAL COUNSEL

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February 10, 2003

Mr. Hasmukh Shah
Manager, Biocides Panel
CCA Work
American Chemistry Council
1300 Wilson Boulevard
Arlington, VA 22209

Re: Commission Proceeding HP 01-3: Petition to Ban Chromated Copper Arsenate (CCA)-Treated Wood in Playground Equipment.

Dear Mr. Shah:

I am providing an initial response to your letter of February 5, 2003 to Todd Stevenson, Secretary to the Commission, concerning the pending proceeding on petition HP 01-3, *Petition to Ban Chromated Copper Arsenate (CCA)-Treated Wood in Playground Equipment.* We will place your comments on the risk assessment and the underlying studies performed by CPSC staff as part of its work in response to that petition into the public docket and fully consider them in that proceeding.

However, allow me to correct an apparent misconception concerning our staff's efforts which I am assured are, as of this date, "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed studies and supporting studies." CPSC Information Quality Guidelines at page 7.[1] In addition to being reviewed by EPA scientific and technical staff within that agency's Office of Pesticide Programs, the risk assessment and supporting work performed by CPSC staff were subjected to external peer review. Also, you will recall that, at the behest of EPA, last summer Commission staff reviewed and commented on the draft protocols developed by your organization for the studies mentioned in your letter to help assure that data generated from them would be useful in adding to the knowledge base on CCA-related exposure issues developed by CPSC staff.

[1] The Commission's information quality guidelines established as required by Public Law 106-554 are available on the world wide web at : http://www.cpsc.gov/library/infoguidelines.html

Let me briefly address your reference to the Commission's Information Quality Guidelines. As I am sure you are aware, the Guidelines, the final version of which reflect changes made in response to comments by the Office of Management and Budget, provide an administrative procedure by which to request correction to information disseminated by CPSC that a party believes does not comply with CPSC's or OMB's information quality guidelines. Alternatively, as noted in the Guidelines, in a Commission rulemaking, public notice and comment procedures as mandated by the Administrative Procedure Act are available to the American Chemistry Council and other interested parties.

Rest assured that when the staff's briefing package on petition HP 01-3, including the risk assessment and supporting memoranda, is forwarded to the Commission for its use in considering what action to take on the petition, the American Chemistry Council and other interested parties will have a full and fair opportunity to review and provide input on it. To assist you in that regard, I will ask the Office of the Secretary to assure that you receive a hard copy of the briefing package, which is also available on line at:
http://www.cpsc.gov/library/foia/foia03/brief/cca0.pdf.

Sincerely,

W. H. DuRoss, III

U.S. CONSUMER PRODUCT SAFETY COMMISSION
INFORMATION QUALITY GUIDELINES

The U.S. Office of Management and Budget (OMB) has issued government-wide information quality guidelines under Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554). The OMB guidelines have been prepared to ensure and maximize the quality, utility, objectivity, and integrity of information disseminated by federal agencies. These guidelines direct all Federal agencies to implement their own implementing guidelines by October 1, 2002. OMB's guidelines were published in the Federal Register on September 28, 2001 (66 FR 49718) and updated on January 3, 2002 (67 FR 369). A corrected version of the guidelines was published in the Federal Register on February 22, 2002 (67 FR 8452). In response to the OMB directive, the U.S. Consumer Product Safety Commission (CPSC) issued its Draft Information Quality Guidelines for public comment on April 20, 2002 (67 FR 21222). These draft guidelines contained the scope of the guidelines, description of CPSC's information quality standards, and an administrative mechanism by which the public can seek correction of information disseminated by the CPSC.

This report presents the revised draft of CPSC's Information Quality Guidelines. This revision incorporates applicable comments received from the public and OMB, as well as other changes to fulfill OMB and CPSC requirements for efficiency and effectiveness.

CPSC works to save lives and keep families safe by reducing the risk of injuries and deaths associated with consumer products. CPSC does this by:

- Developing voluntary standards with industry;
- Obtaining the recall of products or arranging for their repair;
- Issuing and enforcing mandatory standards or banning consumer products if no feasible standard would adequately protect the public;
- Conducting research on potential product hazards; and
- Informing and educating consumers through the media, state and local governments, private organizations, and by responding to consumer inquiries.

In meeting its mission CPSC disseminates information in a number of ways, including:

- Press releases and video news releases
- Publications
- Product safety alerts
- Special technical reports
- Advisory opinions
- Regulatory guidance letters

This information is used by the media, the public as well as by other government agencies, to reduce the risk of product-related death and injuries. Businesses use the information to assure that products they manufacture or import comply with the requirements of applicable regulations and to discharge the various obligations that the laws the Commission administers impose on firms.

The CPSC Information Quality Guidelines substantially follow the provisions of the OMB guidelines referenced above. Under the OMB information guidelines three aspects of quality must be considered: utility, objectivity, and integrity. In addition, for influential data, higher standards of transparency and reproducibility must be met. CPSC's guidelines use the definitions of the key statutory terms such as "information," "disseminate," "utility," "objectivity," "integrity," "influential," "transparency," and "reproducibility" as defined in the OMB guidelines. For the purpose of these guidelines, most of the information disseminated by CPSC does not meet the standard of influential as defined by the OMB guidelines. Each of these aspects of quality is described below.

Utility

Utility involves the usefulness and availability of the information for its intended use. Utility is achieved by continuously monitoring information and developing new information sources or by revising existing information collection methods, models, and information products where appropriate.

CPSC efforts to ensure the usefulness of information include:

- Internal analyses and review of information requirements and products
- Discussions with policy-makers and analysts at all levels of government
- Consultations with data providers and data users
- Preparation of "plain English" guides and summaries of information

CPSC efforts to ensure the availability of information include:

- Participation in industry-sponsored and government-sponsored meetings, conferences and workshops
- Exploring and implementing multiple vehicles with which to disseminate information
- Providing expanded Web site access to publicly available information

Objectivity

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, and by carefully reviewing the content of all information products.

- Use of reliable data sources

CPSC is a data-driven agency and bases its decisions on the data it collects to assess the causes and scope of product-related injuries and deaths. Many of the information products disseminated by CPSC are created using information in death, injury and compliance action databases. These databases contain information used to perform standards effectiveness studies, special investigation studies, emerging hazard evaluation and other technical analyses. CPSC conducts ongoing internal quality assurance reviews of information in its

database systems. These reviews include checks for accuracy, completeness, and consistency to ensure high quality. Often these databases contain information from external sources. Data and procedures are reviewed to ensure that data from external sources are properly transferred into the database.

When analysis requires using samples from databases, CPSC employs statistically acceptable methods to design and select the samples. Data samples are designed and compiled by staff knowledgeable about the content, structure, and limitations of the administrative data files employed. In addition, those staff members maintain working relations with agency personnel who create, update, and maintain those files to ensure that their understanding of files is current and complete. When information products require administrative files linked to external data sources, CPSC employs sound procedures for extracting and linking data from external sources based on a thorough understanding of the relevant components of the data sources.

Occasionally CPSC conducts surveys of product use, customer satisfaction, and service quality. CPSC employs and documents accepted professional standards and practices for all survey activities, including sample frame development, sample design, questionnaire design and testing, data collection, analysis of sampling and coverage errors, imputation of missing data, weighting, and variance estimation. CPSC surveys follow guidelines and policies set forth in the Paperwork Reduction Act and other regulations related to the conduct of government surveys. CPSC is already required to demonstrate in their Paperwork Reduction Act submissions to OMB the `practical utility' of a proposed collection of information the CPSC plans to disseminate. Additionally, for all proposed collections of information that will be disseminated to the public, CPSC should demonstrate in their PRA clearance submissions to OMB that the proposed collection of information will result in information that will be collected, maintained, and used in a way consistent with OMB and CPSC information quality guidelines.

CPSC information products may also include data produced or maintained by other U.S. government agencies or other private organizations. All such information is assessed by CPSC prior to its use. Third party information may be included in information that CPSC disseminates. Although third-party sources may not be directly subject to OMB's information quality guidelines, when used by CPSC to develop information products, this information must follow CPSC's information quality guidelines.

- Use of sound analytic techniques

CPSC analytical reports are prepared using a variety of analytical techniques including simple tabulations with descriptive summary statistics and multivariate statistical methods. For example, these reports can include integrating injury and incident information with laboratory testing and analysis, assessment of human exposure to various risks, and correlation of human behavior and risk. Analytical techniques are reviewed by qualified staff for their appropriateness to the data and the analysis being conducted and are clearly identified in reports.

CPSC also conducts economic studies, developing injury cost projections to estimate

potential benefits associated with CPSC actions. These projections are based on standard techniques and utilize the most relevant and up-to-date information available.

CPSC occasionally utilizes models to conduct engineering analyses and forecast product injury information. Most models utilized by CPSC have been developed by CPSC staff or by CPSC contractors under direction from CPSC. When CPSC uses a proprietary model from another organization, CPSC undertakes an analysis of the model to ensure its appropriateness before including the model results as part of a CPSC information product. CPSC models have detailed documentation describing the goals and objectives of the model, the data sources being used and the methodologies and assumptions employed. CPSC models are based on best judgments of current and future behavioral relationships and methods of projection. The models are periodically updated to reflect input from internal and external reviews and research findings on behavioral relationships. Any updates are documented.

- Preparation of information products

CPSC information products are based on internal data and analyses, surveys, models, and external information sources. Appropriate procedures are used in all steps of the information product preparation process. Documentation available with CPSC information products is designed to improve understanding of the information so that users may assess the suitability of the information for their needs. Reports are prepared by staff using a variety of sound analytical techniques ranging from simple tabulations and descriptive summary statistics to multivariate statistical methods and econometric models. Staff members preparing analytic reports and policy studies are knowledgeable in their use of relevant administrative data files, external data sources, and projections from simulation models.

- Review prior to dissemination

Information products are reviewed by technically qualified staff prior to dissemination to ensure their quality. Products that are considered to be more technically complex may also be reviewed by independent expert reviewers to provide additional perspective and expertise. The level of review an information product is subjected to prior to dissemination is determined by the characteristics of the product and CPSC-established review procedures. (See 15 U.S.C. 2055(b)(6) and CPSC Directive 1450.2.) Analytical techniques are clearly described and data sources are identified in reports. When analyses are based on projections from models, the assumptions used to produce the projections are identified, as well as the rationale for the assumptions used and the impact of using alternative assumptions. By statute, if the information disseminated by CPSC publicly identifies the manufacturer of a product, CPSC provides the manufacturer with the opportunity to comment on the accuracy of the information.

- Policy for correcting errors and revising previously disseminated information

CPSC's information may be revised after initial dissemination to reflect more complete information, corrections or other changes. CPSC information products identify information

that is preliminary and expected to be revised as well as revisions made to information previously disseminated.

Integrity

Integrity, as used in the OMB quality guidelines, refers to the security of information from unauthorized access or revision to ensure that the information is not compromised through corruption or falsification. CPSC is highly protective of the confidentiality of information it holds through its policies and practices.

To ensure the integrity of its administrative information, CPSC will employ rigorous controls that have been identified as representing sound security practices. CPSC has in place programs and policies for securing its resources as required by the Government Information Security Reform Act (P.L. 106-398, title X, subtitle G). Those security procedures address all major components of information security and apply to all CPSC operating components. In addition, CPSC is subject to statutory requirements to protect the sensitive information it gathers and maintains on individuals. Those requirements are contained in the following documents:

- Privacy Act of 1974
- Freedom of Information Act
- Computer Security Act of 1987
- Office of Management and Budget (OMB) Circulars A-123, A-127, and A-130
- Government Information Security Reform Act
- Federal Managers' Financial Integrity Act (FMFIA) of 1982

Transparency and Reproducibility

CPSC's Information Quality Guidelines substantially follow the definitions for "influential," "transparency," and "reproducibility" as defined in the OMB Guidelines referenced above. OMB's guidelines state that information disseminated by Federal agencies is considered "influential" if it does or will have a clear and substantial impact on important public policies or important private sector decisions. OMB's guidelines require that agencies disseminating influential information must have quality guidelines that include a high degree of transparency about data and methods to facilitate reproducibility of such information. "Reproducibility" as set forth in the OMB guidelines' means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision.

Most of the information disseminated by CPSC does not fall under OMB's definition of "influential." However, CPSC's staff and contractor technical reports related to engineering, health science, or hazard analysis issues potentially have impacts on important public policies and private sector decisions, such as changes in voluntary standards. Therefore, CPSC's information in these reports should be highly transparent and capable of being reproduced by qualified persons. CPSC strives for a high degree of transparency about information and methods in order to improve understanding and to facilitate reproducibility by qualified third parties. To achieve transparency and reproducibility, CPSC's Guidelines

require documentation of systems and models and appropriate explanatory material to accompany disseminated information (specific data sources and quantitative methods and assumptions used). Some estimates and projections included in CPSC's information products are not directly reproducible by the public because the underlying data sets used to produce them are confidential. Also, some estimates and projections may not be easily reproducible by third parties due to the complexity and detail of the methods and data. CPSC places great emphasis on its review process to ensure the quality of information disseminated.

CPSC also achieves transparency through wide dissemination of its information. Most reports and other data products are available both as printed and electronic documents. They are announced on the CPSC web site and most electronic versions can be accessed and downloaded directly from the web site.

To ensure reproducibility, CPSC creates archival files of data and model results that are used as input to CPSC information products.

Risk Assessment

Some of the influential information that we disseminate is based on an analysis of the risks to the public of certain actions or exposures to hazardous substances. For purposes of this guidance, we are defining risk as the likelihood that injury or damage is or can be caused by a substance, technology, or activity. We use risk analysis (the integration of risk assessment with risk management and risk communication) as a tool to enhance the scientific basis for our regulatory decisions.

The OMB Guidelines provide special considerations that must be taken into account in certain risk assessments, those that provide the basis for the dissemination of influential information. The Guidelines state that "With regard to analysis of risks to human health, safety, and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (SDWA) (42 U.S.C. 300g-1(b)(3)(A) and (B))."

The SDWA risk assessment principles are as follows:

1. To the degree that the agency action is based on science, the agency shall use
    a. the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices
    b. data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data)
2. In the dissemination of public information about risks, the agency shall ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.
3. In a document made available to the public in support of a regulation, the agency shall specify, to the extent practicable
    a. Each population addressed by any estimate of applicable risk effects

b. The expected risk or central estimate of risk for the specific populations affected
c. Each appropriate upper-bound or lower-bound estimate of risk
d. Each significant uncertainty identified in the process of the assessment of ris effects and the studies that would assist in resolving the uncertainty and
e. Peer-reviewed studies known to the agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile the inconsistencies in the scientific data.

Many of our actions are based on scientific experts' judgments using available data, are essentially qualitative, and are generally carried out for non-cancer-causing hazards. Such assessments provide useful answers in most instances that are sufficient for regulatory purposes, and much more elaborate, quantitative estimates extrapolating beyond the data are unnecessary. Although we might analyze the economic costs of the regulations and consider alternatives, regulations like these do not lend themselves to the types of full quantitative risk assessments contemplated by the Safe Drinking Water Act principles. As a result, we have adapted the general principles for risk assessments from the SDWA to fit these situations. The principles we intend to apply to risk assessments involving the dissemination of influential information affecting product approval actions or regulations that do not lend themselves to quantitative risk assessment are as follows:

1. The Agency will use —
   a. the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed studies and supporting studies where available
   b. data collected by best-available method or accepted methods (if reliability of the method and the nature of the decision justify use of the data)
2. In the dissemination of public information about risks, the Agency will ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.

CPSC rarely performs quantitative risk assessments. However, in situations requiring a quantitative risk assessment, we generally follow basic risk assessment principles in the NAS paradigm of 1983. Thus, we also subscribe to the statement from NAS when it revisited the risk assessment process in 1994 *(Science and Judgment in Risk Assessment,* NAS 1994): "Risk assessment is not a single process, but a systematic approach to organizing and analyzing scientific knowledge and information." In each of the areas we regulate, we apply risk assessment practices to the specific task that are widely accepted among relevant domestic and international public health agencies.

For quantitative risk assessments in support of the dissemination of influential information, CPSC intends to apply the following principles, following the SDWA risk assessment principles:

1. The agency will use —
   a. the best available science and supporting studies conducted in accordance with sound and objective scientific practices;

b. data collected by accepted methods (if reliability of the method and the nature of the decision justifies use of the data)

2. In the dissemination of public information about health risks, the agency shall ensure that the presentation of information is comprehensive, informative, and understandable, within the context of its intended purpose.
3. In a risk assessment document made available to the public, the agency shall specify, to the extent practicable —
   a. Each population addressed by any estimate of applicable effects;
   b. The expected or central estimate of risk for the specific populations affected;
   c. Each appropriate upper-bound and/or lower-bound risk estimate;
   d. Data gaps and other significant uncertainties identified in the process of the risk assessment and the studies that would assist in reducing the data gaps and other uncertainties; and
   e. Additional studies not used to produce the risk estimate that support or fail to support the findings of the assessment, the rationale of why they were not used, and the methodology used to reconcile the inconsistencies in the scientific data.

Information Not Subject to CPSC's Information Quality Guidelines

CPSC's Guidelines do not apply to:

- Procedural, operational, policy, and internal manuals prepared for the management and operations of the agency that are not primarily intended for public dissemination.
- Information disseminated by CPSC employees that is not put forth as a CPSC product (e.g., materials presented by an individual at a professional meeting).
- Other materials specifically exempted in the OMB guidelines

CPSC has historically utilized standards, policies, and other operational guidance to ensure the quality of all its activities and has confidence in the quality of information disseminated by CPSC prior to October 1, 2002. However, we regard information originally disseminated before October 1, 2002, as being subject to these information Quality Guidelines only if it remains readily available to the public, (e.g., it is posted on the CPSC Web site) and it continues to play a significant, active role in CPSC programs or decisions.

Administrative Correction Mechanisms

CPSC has established procedures for any person to request correction to information disseminated by CPSC when the information does not comply with CPSC's or OMB's information quality guidelines. A person who believes that information disseminated by CPSC does not adhere to CPSC's or OMB's information quality guidelines and who would like to request correction of specific information should write to the Office of the Secretary, U.S. Consumer Product Safety Commission, Washington, D.C. 20207, or send an e-mail to cpsc-os.gov or use the form at http://www.cpsc.gov/feedback.html. The Request should be captioned "Information Quality Guidelines" and should provide the following information:

- Information identifying the requestor;
- A specific description of the information to be corrected;

- Potential adverse impacts from the information identified for correction; and>/li>
- A specific reason why and how the information should be corrected.

Based on a review of the information provided, CPSC will take the following actions:

- Perform an acceptance review to confirm that the necessary information regarding the correction has been provided.
- Submit the request for review to a management official who is knowledgeable about the subject matter related to the request. The designated management official may consult with other federal agencies or CPSC staff in responding to the request for correction, as appropriate.
- Determine whether a correction is warranted and, if so, what action will be taken.
- Respond to request for correction of information within 60 calendar days of receipt of the request. If the request requires more than 60 calendar days to resolve, then CPSC will inform the requestor that more time is required, state the reason why, and include an estimated decision date.

If the requestor is not satisfied with CPSC's final response to the request, the requestor may submit an appeal to the Office of the Executive Director, U.S. Consumer Product Safety Commission, Washington, D.C. 20207. The requestor must use the following process to appeal a decision:

- Submit an appeal within 30 calendar days of receipt of CPSC's notification of denial or notification of the corrective action. (Only the original requestor may appeal the decision.)
- Identify the original request for correction, and specify the CPSC response that they are appealing.
- Describe the basis for the appeal and how the response failed to resolve the request for correction.

The appeal will be evaluated by an agency official, typically at the Executive Director level. The appeal review will be limited to the basis of the appeal. The requestor will be notified of the agency's decision regarding the appeal within 60 calendar days. If the request requires more than 60 calendar days, then CPSC will tell the requestor that more time is required, state a reason why, and include an estimated decision date.

The correction and appeal process that will address data quality challenges does not apply to information disseminated by the CPSC through a comprehensive public comment process, e.g., Federal Register notices of proposed rulemakings, regulatory analyses, requests for comments on information collections subject to the Paperwork Reduction Act, environmental impact statements, and other documents for which CPSC solicits public comments. Persons questioning the quality of information disseminated in those documents, or documents referenced or relied upon in those documents, must submit comments as directed in the Federal Register or other notices requesting public comment on the given document. CPSC will use its existing processes for responding to public comments in addressing the request for correction, and will describe the actions it has taken with regard to the request in the Federal Register notice of the final agency rule, regulatory

analysis, or other final action. In cases where the agency disseminates a study, analysis, or other information prior to the final agency action or information product, requests for correction will be considered prior to the final agency action or information product in those cases where the agency has determined that an earlier response would not unduly delay issuance of the agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination if the agency does not resolve the complaint prior to the final agency action or information product.

The correction process is designed to address the genuine and valid needs of affected persons without disrupting agency operations. The requestor should be aware that they bear the burden of proof with respect to both the need for correction and the type of correction requested. In determining whether to correct information, CPSC may reject claims made in bad faith or without justification. The CPSC is required to undertake only the degree of correction that it concludes is appropriate for the nature and timeliness of the information involved.

References

1. Office of Management Budget Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. Final Guidelines. Effective January 3, 2002. http://www.whitehouse.gov/omb/fedreg/reproducible.html
2. Saving Lives and Keeping Families Safe: 2002 Performance Plan, U.S. Consumer Product Safety Commission, Operating Plan, January 2002, http://www.cpsc.gov/about/gpra/2002Plan.pdf.
3. Clearance Procedures for Providing Information to the Public, U.S. Consumer Product Safety Commission, Directive 1450.2, September 5, 2001, http://www/cpsc.gov/library/1450.2.html.
4. Public Disclosure of Information, 15 U.S.C. Sec. 2055, http://www4.law.cornell.edu/uscode/15/2055.html
5. Science and Judgement in Risk, National Research Council, National Academy Press, 1994, http://www.nap.edu/books/030904894X/html/index.html.

American Chemistry Council Good Chemistry Makes It Possible

IQ 03-1

February 5, 2003

VIA FASCIMILE

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

RE: Information Quality Guidelines

Dear Mr. Stevenson:

I write on behalf of the American Chemistry Council Biocides Panel CCA Work Group (the Work Group) to raise serious concerns about the Consumer Product Safety Commission's (CPSC's) conduct of a study involving wood treated with Chromated Copper Arsenate (CCA). The conduct of this study, and any reliance by CPSC on this study for risk assessments or regulatory decisions, is likely to conflict with the information quality guidelines of section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554), and the Office of Management and Budget's (OMB's) and CPSC's guidelines implementing this law.

As background, the Work Group has been working with the Environmental Protection Agency's (EPA's) Office of Pesticide Programs in connection with appropriate regulation of arsenical wood preservatives and wood treated with those preservatives. Recently, questions have arisen concerning the need to quantify the exposure to arsenic that might be encountered by users of treated wood structures, such as decks. In response to these questions, the Work Group has worked with EPA to develop protocols and conduct studies budgeted to cost approximately $1.5 million. These studies seek to quantify the amount of dislodgable surface residue removed from wood treated with CCA wood preservative using both cloth wipes and actual human hand contact. They also examine the bioavailability of arsenic from surface residue and soil containing inorganic arsenic. These rigorous, well-controlled studies are scheduled to be completed late this Spring. EPA is scheduled to complete a risk assessment on treated wood early this fall.

CPSC has recently become interested in CCA treated wood, and the Work Group has endeavored to work with CPSC. Considering the effort already expended by EPA and the Work Group into studying CCA wood preservative, and the possibility of contradictory or duplicative regulation, the Work Group members have worked to coordinate CPSC's studies and decision making with that of EPA.

Recently, the Work Group has learned that CPSC has conducted a relatively small, uncontrolled study of dislodgable residue from CCA treated wood using cloth wipes. The Work Group understands that this study currently exists only in draft form and is under review by CPSC. The Work Group also understands that, even though the study has been shared with certain individuals at EPA, who have provided comments critical of CPSC's methodology, it has not been subject to external peer review. The Work Group understands that the CPSC intends to release the results of this study, and rely upon this study to perform a risk assessment and initiate regulatory action with respect to CCA treated wood, in the very near future. CPSC staff have indicated that they will initiate regulatory action without the benefit of the more comprehensive and reliable studies conducted under EPA's guidance that are nearing completion.

The Work Group believes that dissemination of CPSC's study, or the initiation of any regulatory action based on this study, likely is inconsistent with both OMB's and CPSC's guidelines for ensuring the quality of data and information relied upon by Federal agencies. As a preliminary matter, the Work Group believes that data regarding CCA treated wood should be treated as "influential data" under OMB's and CPSC's guidelines, and therefore be subjected to the highest level of scrutiny for quality and reliability. *See* 67 Fed. Reg. 8452, 8460 (February 22, 2002). As CPSC has acknowledged, assessments of risks to the public from exposures to potentially hazardous substances should be measured by higher standards of objectivity, transparency, and reliability. *See* CPSC Information Quality Guidelines at 6.

Specifically, the Work Group believes that any risk assessment or regulatory action based principally on the CPSC study could violate the CPSC's commitment to use "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed studies and supporting studies" and only "data collected by the best-available method or accepted method...." CPSC Information Quality Guidelines at 7; *see also* 67 Fed. Reg. at 8454 (noting presumption favoring formal, independent, external peer review for scientific information).

Moreover, given the fact that more comprehensive and reliable studies – conducted under the supervision of another Federal agency – already are in progress, any regulatory action or dissemination of information regarding risks of CCA treated wood may directly contradict CPSC's commitment to "ensure that the presentation of information about risk effects is ***comprehensive***, informative, and understandable." CPSC Information Quality Guidelines at 8 (emphasis added). CPSC action based on exposure data from one small study can not be considered comprehensive, especially when EPA may disseminate differing or contradictory results from its more thorough studies only months later.

We recognize that CPSC's formal procedures for requesting correction of data appear to apply only to information that has already been disseminated by CPSC. However, the Work Group wishes to bring this matter to the Commission's attention while it is still possible to effectively avoid the problem. Once CPSC's study is disseminated, there may be serious marketplace effects that cannot be remedied by correction of the information or publication of more comprehensive study results at a later date.

EPA and the Work Group have requested CPSC staff to consider the data currently being developed for EPA, and to develop its own data with similar quality safeguards. However, CPSC staff have not responded in a meaningful way.

Therefore, the Work Group requests that, to ensure compliance with OMB and CPSC's Information Quality Guidelines, CPSC refrain from prematurely disseminating the data developed by CPSC, or commencing any regulatory action based on this data, until it may be subjected to "formal, independent, external peer review" and considered in context with the more rigorous study being conducted for EPA.

I look forward to discussing this matter with you.

Sincerely,

Hasmukh Shah

Hasmukh Shah
Manager, Biocides Panel
CCA Work Group

cc: Chairman Hal Stratton
Commissioner Mary Sheila Gall
Commissioner Thomas Moore
William DeRoss
James Fuller
John D. Graham, Ph.D., Director, Office of Information and Regulatory Affairs, Office of Management and Budget
Nancy Beck, Office of Management and Budget