DATE: OCT 9 2003

TO: The Commission
    Todd A. Stevenson, Secretary

THRU: W. H. DuRoss, III, General Counsel
       Stephen Lemberg, Assistant General Counsel for Regulatory Affairs

FROM: Lowell F. Martin, Attorney-Advisor, GCRA (ext. 7628)

SUBJECT: Petition to Ban Use of Chromated Copper Arsenate (CCA)-Treated Wood in Playground Equipment (Petition No. HP 01-3)

The staff, in the attached memorandum, recommends that the Commission deny the subject petition and direct the staff to continue efforts to identify stains and sealants to reduce exposure to arsenic from CCC-treated wood structures.

Please indicate your vote on the following options.

I. DENY THE PETITION AND APPROVE THE DRAFT LETTER ATTACHED TO OGC MEMORANDUM AS DRAFTED

(Signature)                                      (Date)

NOTE: This document has not been reviewed or accepted by the Commission.
Initial(s) Date 10/9/03


Draft Document CLEARED for Public

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EXCEPTED BY: PETITION RULEMAKING ADAM P.

WITH PORTIONS REMOVED.
II. DENY THE PETITION AND APPROVE THE DRAFT LETTER WITH CHANGES
(Please specify)

(Signature)                      (Date)

III. OTHER (Please specify)

(Signature)                      (Date)

Attachment: Memorandum from Jacqueline Elder and Patricia Bittner to the Commission of September 29, 2003, HP 01-3, Petition to Ban the Use of CCA-Treated Wood in Playground Equipment, and attachment thereto.
Memorandum

TO: The Commission
    Todd A. Stevenson, Secretary

THROUGH: W.H. DuRoss, III, General Counsel
    Patricia M. Semple, Executive Director

FROM: Jacqueline Elder, Assistant Executive Director, Office of Hazard
      Identification and Reduction
      Patricia M. Bittner, M.S., Project Manager for Chromated Copper
      Arsenate (CCA)-Treated Wood in Playground Equipment, Directorate
      for Health Sciences  301-504-7263

SUBJECT: HP 01-3, Petition to Ban the Use of CCA-Treated Wood in Playground
          Equipment

This package presents the staff responses to written questions from Commissioner
Moore, and to written and oral public comments on the CPSC staff briefing package on
the petition to ban the use of CCA-treated wood in playground equipment (HP-01-3)
(Tab A). This package also contains a staff memorandum that provides an analysis of
the EPA final cancellation notice for the pesticide registration of CCA (Tab B).

In February 2003, the staff forwarded a briefing package to the Commission addressing
petition HP 01-3. Since that time, there has been no new, or anticipated, scientific
information that alters the technical staff's conclusion that there is an increased lifetime
lung or bladder cancer risk of about 2 to 100 per million for a person who plays on CCA-
treated wood playground structures during early childhood. In the February package,
the staff recommended that the Commission defer action on the petition until EPA
completed its action to cancel the CCA pesticide registration and the staff assessed the
impact of that action. Based on the staff's assessment of the scope of the cancellation,
CCA will no longer be used to treat wood for most consumer uses after the end of 2003,
and it is expected that CCA-treated wood for these uses will be out of the retail stream
by June 2004. The cancellations finalized by EPA will result in changes in the
preservative-treated wood market, irrespective of any action taken by the Commission
with regard to the petition. In fact, the cancellation by EPA addresses the action
requested by the petitioners. Furthermore, most major commercial and residential
manufacturers of wood playground equipment have already stopped using CCA-treated
wood to make their products.
CPSC and EPA staff are currently working to identify stains and sealants that can be used on CCA-treated wood structures to minimize the amount of arsenic leaching from the wood.

Based on the above considerations, the staff recommends that the Commission deny the petition and direct the staff to continue efforts to identify stains and sealants to reduce exposure to arsenic from CCA-treated wood structures.
DATE: September 5, 2003

TO: Jacqueline Elder, Assistant Executive Director, Office of Hazard Identification and Reduction

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences
Susan Ahmed, Ph.D., Associate Executive Director, Directorate for Epidemiology
Dale Ray, Acting Associate Executive Director, Directorate for Economic Analysis

FROM: Kristina M. Hafleid, Ph.D., Toxicologist, Directorate for Health Sciences
Patricia M. Bittner, M.S., Toxicologist, Directorate for Health Sciences
Treye A. Thomas, Ph.D., Toxicologist, Directorate for Health Sciences
Robert Franklin, M.S., Economist, Directorate for Economic Analysis
Mark S. Levenson, Ph.D., Directorate for Epidemiology

SUBJECT: Response to Questions Posed by Commissioner Moore and Public Comments on Petition HP-01-3 to Ban the Use of Chromated Copper Arsenate (CCA)-Treated Wood in Playgrounds

This memorandum provides staff responses to written questions posed by Commissioner Moore and public comments made to the U. S. Consumer Product Safety Commission (CPSC) regarding petition HP-01-3. This petition requests a ban on the use of CCA-treated wood in playground equipment. The Commission docketed the petition in June 2001 and published a Federal Register notice on July 13, 2001 requesting public comments by September 11, 2001 (66 FR 36756). CPSC staff developed a briefing package that included an assessment of risk from the use of CCA-treated playground equipment by children and an analysis of public comments, which was made public on February 7, 2003. The Commission published a Federal Register notice on February 14, 2003 that requested public comments on this briefing package (68 FR 7510) (Appendix A). Staff briefed the Commission on the petition at a public meeting that included public participation on March 17-18, 2003. There were a total of 84 comments from various sources including consumers, the wood industry, environmental groups, and trade associations. A complete listing of commenters is presented in Appendix B.
Staff Response to Commissioner Moore's Questions

1) In determining the amount of arsenic children ingest, staff made the assumption that children put both hands in their mouths. On what basis did you make that assumption? When you talk about "hands" aren't you really talking about fingers? At the staff briefing, Dr. Hatlelid stated that she thought most of the arsenic residue would be on the child's fingertips, rather than on the palm. On what is this assumption based?

Response: To determine children's exposure to chromated copper arsenate (CCA) from playground equipment, staff considered the amount of arsenic that was removed from the wood surface onto the hand and then the portion of that arsenic from the hand that would be ingested. The staff assumed that some of the residue that collects on both hands may be transferred to the mouth. The staff's assessment was based on both hands of a child under the assumption that children use both hands to touch and grasp playground equipment wood during play and that they use both hands to handle toys and food. However, the staff's method for calculating exposure did not require measuring the specific characteristics of residues on children's hands, or estimating specific children's behaviors or activities. To calculate the amount of arsenic that comes off the wood onto the hand, staff used data from the CPSC staff's field studies in which adult volunteers used one hand to sample the wood surface. Since the size of an adult hand is approximately the same as the size of two hands of a child, the staff used the results of the adult study to represent the exposure for a child using both hands during play.

The second part of the exposure assessment estimated the amount of residue on the hands that would be transferred to the child's mouth. The staff estimated this exposure based on the approach that arsenic residue on the surface of the wood would be transferred to the child's hands during play and then a proportion of that "handload" would be transferred to the child's mouth during the day. This approach does not rely upon an estimate of the portion (or size) of the hands involved in each hand-to-mouth event, the number of times children contact their mouths with their hands, or the portion of residue on the contacted hand surface area that is ultimately transferred from the hands to the mouth during each event. It does not require that any specific activity occurs or that any specific activity be measured. Rather, staff believes the approach it used approximates actual exposures in that it includes incidental and indirect hand-to-mouth contact as expected during normal childhood activities (e.g., handling of toys and food), in addition to direct mouthing of the hands (e.g., thumb-sucking).

The staff did not need to explicitly quantify any particular mouthing behaviors, such as putting "hands" or "fingers" directly in the mouth because we used an empirical method that has been used in other CCA risk assessments to derive hand-to-mouth transfers, based on the analogy with children's soil exposure and ingestion. The data used in this method are derived from the published scientific literature (Hatlelid, 2003b; Lee, 1990a; Gradient, 2001). Whatever the ingestion pathway for soil (i.e., from fingers, palms, mouthing toys, eating snacks, etc.), we have information on the total daily soil intake. Dividing the average total daily soil intake by the average amount of soil known to stick
to both hands yields the proportion of a "handload" that is ingested. Where that soil was found on the hands or how it was ingested is irrelevant to this final proportion.

Based on the physical characteristics of hands, and observations by the staff during the human volunteer sampling using polyester "mittens", the staff believes that it is unlikely that residues are spread evenly across the hand’s surface. Rather, more residues likely collect on the fingers, thumbs, heel of the hand, and base of the fingers than on the palm itself. Those parts of the hands, especially thumbs and fingers, are more likely to be involved in touching and transferring residues to objects or food, and are more likely to be involved in direct hand-to-mouth contact than the large portion of the central palm area. However, as explained above, the staff’s approach to estimating the hand-to-mouth transfer of residues does not require that we measure the distribution of residues across the hands or that we measure any specific activities that would be involved in ingestion of the residues.

2) Based on our understanding of the research that EPA is doing, will they have enough solid data on all the key input parameters to do a probabilistic assessment?

Response: Based on the staff's understanding, we do not believe the new research will provide enough data for all the input parameters. As we understand it, research is being done on two areas of interest to CPSC staff (bioavailability and dislodgeable arsenic levels on wood surface), which will add to the knowledge base, but likely will not provide all the distributions needed for probabilistic modeling.

There are two general approaches to risk assessment modeling: deterministic and probabilistic. These are both valid mathematical approaches for estimating risk. The key difference between these approaches is that deterministic modeling enters point estimates for the model parameters while probabilistic modeling uses distributions. Probabilistic and deterministic approaches can be expected to produce similar results for the mean risk, but the probabilistic approach can provide information on the distribution of risks over the population. While a benefit of modeling using distributions is the ability to quantify uncertainty, uncertainty also can be evaluated in deterministic modeling by conducting separate uncertainty analyses. In addition, the probabilistic approach provides a benefit to the risk assessor only when there are sufficient data on the distributions of the critical input parameters.

Several studies have been conducted by the industry in coordination with EPA and are currently at the EPA for review. One of these studies provides additional information on the amount of arsenic residue that transfers from the CCA-treated wood surface to the hands. Results reported in a preliminary abstract on this study indicate that dislodgeable arsenic levels do not differ substantially from the residue levels found by CPSC staff (Gutknecht et al., 2003). This information will add to the work by the CPSC staff, as well as others in the U.S. and Canada.

The other industry study involves bioavailability of arsenic in animals from the wood surface residues. While this information will help in our understanding of the characteristics of the residues, one study in animals, by itself, will not provide enough information to extrapolate to humans or to develop a robust distribution of values for this
variable. Preliminary data from this study indicate that the bioavailability of dislodgeable arsenic residue from CCA-treated wood in swine after oral dosing, while different from the default value used by the staff, is within the range of bioavailability values applied in the CPSC staff sensitivity analysis (Casteel et al., 2003 [abstract]). The results of these industry studies will be used by EPA in its draft risk assessment that will be presented to the EPA Science Advisory Panel in late fall, 2003.

In addition, other parameters in the CPSC staff’s risk assessment and in the EPA assessment will not have any additional data generated by any current or proposed study. In fact, hand-to-mouth transfer of residues, perhaps the most important exposure parameter, will not be studied at all.

The staff cannot say for certain how much new data will be required to conduct a strong probabilistic assessment, but the current studies are not likely to provide enough data for all the critical input parameters. EPA has reviewed a number of new studies on arsenic in soil, soil bioavailability, dermal absorption of wood residues, the fixation of chromium, etc. Data from these studies will be used by EPA in their probabilistic risk assessment, which is based on some pathways (soil), routes of exposure (dermal), and chemicals (chromium) that were not included in the CPSC staff risk assessment.

3) I noticed in the Phase IV Study—Playgrounds, that for short boards only one sample wipe could be performed per board and that an adjacent parallel board was sampled to complete the wet/dry wipe sample scheme. Given the great variability that can exist between boards in the same structure, how does this affect the results of these tests?

**Response:** The purpose of the Phase IV sampling was to obtain a central value of dislodgeable arsenic representing a variety of in-use play structures. Staff recognizes that individual structures may have variations among boards. However, for the risk assessment, the staff used only the average dislodgeable arsenic value obtained from the dry polyester wipes. This average value has lower variation than individual measurements on the boards of the play structures. Because only the dry polyester wipe results were used, differences between the values of the wet and dry wipes on each structure do not affect this average.

4) Is pressure-treated wood treated differently in different parts of the country, either as to application process, the amount of arsenic used, or the formula used to make CCA?

**Response:** According to information received by CPSC staff from the CCA chemical industry (Quinn 2003), the variability in the amount of arsenic found in CCA-treated lumber is due to several factors, including the formulation of CCA preservative used, the level of CCA retained in the wood, the treatment process, and the species of tree used to produce the lumber. For example, it may take longer to treat some species of tree to a certain retention level than other species. Thus, retention levels will vary by wood species, which will vary by geographic location. On the other hand, staff review of the data from studies conducted in several regions of the U.S. (e.g., California, Connecticut)
found that when similar methods were used to measure dislodgeable arsenic on the surface of CCA-treated wood structures, the results were similar (Thomas, 2003).

5) Can you explain the importance of whether arsenic's mechanism of carcinogenicity produces a linear or nonlinear (or a sublinear) response? Dr. Frost stated that the linear relationship that staff assumed between dose and response is “not even considered by the EPA to be the most plausible relationship between arsenic exposure and cancer risks...” Is this true, and if so, why did we assume a linear response?

Response: EPA did not assume a nonlinear or sublinear relationship for the dose response, but, like National Research Council (NRC), chose a linear extrapolation for response at low doses. The staff's assessment was based on quantitative analyses by EPA and NRC.

There are two parts to dose-response modeling and quantitative risk assessment that involve the shape of dose-response relationships. The quantitative analyses of both the EPA and NRC considered both of these parts: 1) modeling the dose-response data from the studies of the exposed populations, and 2) extrapolating from that data to the lower doses expected in the population of interest. Dr. Frost expressed concern about linear curve fitting without clearly addressing the two separate parts of the analyses. EPA and NRC chose to use two different mathematical models to describe the dose-response data from the epidemiology studies of southwest Taiwan, but both chose linear extrapolation from a point on their respective dose-response curves to estimate the low-dose relationship.

In general, the standard methodology involves choosing a point on the dose-response model within the range of observed exposures, such as the dose that is associated with a 1% increase in the excess risk of cancer (called the 1% effective dose or ED01), and extrapolating linearly from that point to the origin (where dose and risk equal zero). The slope of this line is used to calculate the cancer unit risk. In contrast, the dose-response model that is fitted to the observed data may or may not be linear, depending on the data. The extrapolation in the low-dose region (lower than observed exposures in the study population) usually takes the linear form because the true shape of the relationship is unknown.

EPA, in its two FR notices concerning the drinking water rules (proposed rule [EPA, 2000a] and final rule [EPA, 2001]), explicitly described and defended its use of linear extrapolation for low doses. EPA discussed the possible modes of action of arsenic and the evidence that suggests a non-linear dose-response effect. However, EPA acknowledged that because no specific modes of action have been identified for arsenic carcinogenicity, linearity could not be ruled out. EPA stated, “Therefore, in accordance with the 1986 cancer guidelines, and subsequent guidance discussed later, the Agency cannot reasonably use anything other than a linear mode of action to estimate the upper bound of risk associated with arsenic exposure” (EPA, 2001, p. 7005). For similar reasons, the NRC used linear extrapolation.

Thus, while there are multiple modes of action hypothesized for arsenic, there is no one mode that is agreed upon by the scientific community, and a linear relationship cannot
be ruled out. The CPSC staff agrees with the analyses of the available data conducted by EPA and NRC. In addition, this approach is consistent with the Commission’s Chronic Hazard Guidelines.

6) Do you have any information about the ongoing study of mortality from arsenic-related cancers in U.S. counties with elevated levels of arsenic in drinking water that is mentioned in Dr. Frost’s comments? Assuming that this study has no methodological flaws, would its results be helpful in verifying our results?

Response: The staff does not have enough information on ongoing or unpublished studies to assess whether they will be adequate to clearly answer questions of arsenic-related cancers in the U.S.

Regardless of the shape of the dose-response curve, we already have strong evidence for arsenic-related cancers at high doses, and we expect that low exposures are associated with low rates of cancer. However, the cancers known to be caused by arsenic are common cancers that have many potential causes. Therefore, at the relatively low arsenic exposures in the U.S., the corresponding, relatively low rates of arsenic-caused cancer may be difficult to detect in the context of the high rates of cancer due to all causes in this country.

Dr. Frost maintains that it would be feasible to detect excess cancers due to arsenic in the U.S., and refers to a published correspondence (Frost et al., 2002) on the statistical ability to detect arsenic-related cancers. In this letter, the authors discuss some of the difficulties epidemiologists face in studying this issue in the U.S., and they state, "(w)e would agree that a study of current lung cancer risks in the general population could be problematic for water arsenic exposures < 0.050 mg/L." There are populations in the U.S. that consume water containing greater concentrations of arsenic, but even so, these authors mention several potential problems, e.g., the effects of smoking, latency (the length of time between exposure and appearance of the disease), and migration (movement of people into and out of the study area), that investigators and study designs will have to overcome in order to detect the effects.

Because of the numerous difficulties in conducting epidemiological studies, researchers generally prefer to study relatively uncommon diseases, or they conduct the studies in very well-defined populations with exposures that are high enough to characterize accurately and that produce detectable increases in risk.

Other public commenters, including Dr. Beck and Dr. Tsuji (on behalf of the Wood Preservative Science Council), stated during the March 17-18, 2003 public hearing that it would be difficult to detect arsenic-related cancers in U.S. populations due to these issues of low exposures and high background rates of cancer in the U.S.

Without having access to and reviewing the full protocols and the characteristics of the study populations, the staff cannot comment on the adequacy of the methodology in any current or proposed study to overcome potential problems in detecting arsenic-related cancers in the U.S.

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1 16 CFR 1500.135.
7) A number of commenters stated that the daily intake of arsenic estimated by our staff is less than the amount of arsenic that EPA allows in drinking water. Why should we be concerned about a few years’ exposure to a level of arsenic in pressure-treated wood that is less than what the EPA is prepared to allow a child to be exposed every day for his entire life from drinking water?

Response: Several commenters noted that the EPA allows greater arsenic exposure from drinking water than the CPSC staff has estimated could occur from contact with CCA-treated wood playground structures. The staff’s estimate of the average lifetime cancer risk due to exposure to arsenic to people who played on CCA-treated playground equipment during early childhood is in addition to the risk from arsenic from drinking water and other sources. The staff is concerned about arsenic in CCA-treated wood in playground equipment because this particular exposure can result in an increased risk of lung or bladder cancer.

EPA’s drinking water regulations are based on estimates of risk given the current occurrence levels in drinking water in the U.S. (i.e., how much arsenic is actually in U.S. drinking water supplies), because, while some people in the U.S. consume water at the EPA’s maximum allowable level, most Americans are exposed to much lower levels. That is, the population is exposed to a range of arsenic levels up to the specified maximum level, but only a fraction of the population would consume drinking water containing arsenic at concentrations as high as this maximum allowable concentration. Most Americans consume relatively small amounts of arsenic from drinking water. EPA has established 10 µg/L as the maximum allowable level of arsenic in drinking water based on the limitation of technology, cost-benefit analysis, and the data showing that most people will consume water with arsenic levels much lower than this level. The estimated cancer risk at this level is 60 to 300 per million. However, based on the carcinogenicity of arsenic with unknown mode of action, the goal or Maximum Contaminant Level Goal (MCLG) set for drinking water is 0 µg/L.

The CPSC staff estimated an increased lifetime risk of bladder or lung cancer of approximately two to 100 per million due to exposure to arsenic for a person who plays on CCA-treated wood playground structures during early childhood. This is similar to the cancer risk range estimated by EPA for exposure to arsenic in drinking water over a lifetime, and is added to that risk.

8) Dr. Tsuji states that the staff calculations of 3.3 micrograms per day of arsenic should be “corrected” for the number of days per year a child plays on a playset to obtain an average dose over a year of 1.4 micrograms per day. Is she correct? She also states that exposure to playsets for only 5 out of 70 years would result in a lifetime average daily dose of 0.1 micrograms per day. Is that correct?

Response: There are several different ways to express exposure, and we believe that the staff and Dr. Tsuji are both correct, although the exposure estimates are presented in different terms. A common way of estimating exposure for risk assessment is by calculating the lifetime average daily dose, or LADD, which is the total of all of the exposure that occurs divided by the total number of days in a person’s life. The LADD does not mean that we assume that people are exposed every day of their lives —
exposure could be less than lifetime or intermittent. In its risk assessment, the staff calculated the LADD to be 0.0053 μg/kg/day, which is about 0.09 μg/day for a 17.7 kg child (aged 2-6 years). This is similar to the value of 0.1 μg/day presented by Dr. Tsuji.

Another way to present this information is to calculate the exposure for the particular day the activity occurs (e.g., playing on a CCA-treated wood playground structure). In this case, the play day exposure is about 3.3 μg. The average daily exposure through a year of playing on a CCA-treated wood playground structure is estimated by adding all the play day exposures (156 days of 3.3 μg/day) and dividing by the number of days in a year. This calculation results in an average daily exposure over a year of about 1.4 μg. Therefore, the values presented by the staff and discussed by Dr. Tsuji are essentially the same, although the estimates are presented in different terms.

Dr. Tsuji also commented on the relative importance of food and water as sources of exposure to arsenic, and used a bowl of rice as an example of a significant source of arsenic. The staff recognizes that, over a lifetime, arsenic exposures from food, especially certain foods such as rice, other grains, and meats; drinking water; and other sources could be much larger than exposures from playground equipment during childhood. This does not negate the staff conclusion that childhood exposure to arsenic from CCA-treated playground equipment may be associated with an increased lifetime risk of developing lung or bladder cancer. The estimated risk from exposure to arsenic from CCA-treated playground equipment is in addition to the risk of cancer from other sources of arsenic.

9) Dr. Frost indicated that it was very easy to do urinary studies, especially in children, to detect arsenic levels. Have any been done in the U.S. (other than the unpublished ASARCO study)? Would such studies be a more accurate way of assessing arsenic intake levels than making assumptions about ingestion?

Response: The staff is aware of a few studies of arsenic exposure in U.S. children (predominantly environmental exposures such as soil, dust, and water), although none of them were intended to measure specific routes or modes of exposure. Most of the studies were intended to determine if living in certain communities was associated with increased exposure to environmental arsenic. The staff is not aware of any study that looked at a specific source of exposure, such as CCA-treated wood.

Although collecting urine or hair samples involves relatively simple procedures, studies involving humans, especially children, are necessarily complex in design and expensive in order to safeguard the participants and collect meaningful data. The staff believes that for such a study to provide meaningful data, it would require a very robust study design, a sufficiently large sample size, and sophisticated statistics to establish the association between exposure to CCA-treated wood playground structures and urinary or hair arsenic levels. The staff believes that such a study could take years to design and conduct, and would be very costly.

Because arsenic is ubiquitous in our environment, a study to measure exposure from a specific source, such as playground structures, would have to account for all of a child’s daily activities, measure samples of food, water, and beverages consumed and do air, soil and dust sampling. Samples would likely have to be taken repeatedly and over time.
to ensure an adequate accounting of the sources of arsenic for each subject and the
day-to-day variation in intake and excretion that might occur. Since CCA-treated wood
is used for a variety of constructions that children may contact frequently (e.g., picnic
tables, decks, porches, handrailings), investigators would have to carefully ascertain
each subject’s contacts with CCA pressure-treated wood other than playground
structures through observation or diaries.

Another issue is the ability to detect changes in urinary arsenic output associated with
playground exposure. Since the staff’s estimate of average arsenic exposure from
playing on CCA-treated wood playground structures is approximately the same as the
average arsenic intake from food and both will vary about the average (higher and
lower) on a day-to-day basis, it will be very difficult to correlate changes in exposure
from CCA-treated wood playgrounds with urinary arsenic excretion even with accurate
daily diaries/observations. Small amounts of arsenic are also excreted in hair. Hair
levels can be used as a marker for chronic or longer-term exposure, but again,
background sources of arsenic have to be accounted for in order to assign the
measured arsenic to a specific exposure. Further, environmental arsenic that results in
external contamination of the hair is a known problem with this kind of analysis.

Although many children currently play on CCA-treated wood playground structures,
ethical issues must be considered when investigators wish to study exposures that are
suspected to be associated with health risks. This issue is present whether the
investigators actively encourage subjects to engage in specific behaviors or whether
they simply follow subjects engaging in their normal behaviors. Further, consumers
have been warned of the possible hazards associated with exposure to arsenic from
CCA-treated wood through the media and popular press for several years, and we are
currently recommending that children wash their hands after playing, especially before
eating, to reduce their exposures to arsenic-containing residues. If some of the children
recruited for an exposure study have already begun to comply with this advice, some
children’s exposures will be reduced and the results of the study will be difficult to
interpret.

Although it may be difficult to measure or estimate exposure accurately, the staff
believes that the approach chosen provides a reasonable estimate of arsenic exposure,
primarily through ingestion of arsenic-containing residues through hand-to-mouth
contact from CCA-treated wood playground equipment.

10) Mrs. Janak told of her daughter’s neurological problems stemming from
acute arsenic poisoning related to the sanding of their deck. Is everyone
susceptible to this type of reaction to inhaling the dust given off by sanding
pressure-treated wood? Do the neurological problems persist or do they
dissipate with time?

Response: As summarized in the staff’s toxicity review for arsenic (Hatlelid, 2003a),
health effects caused by arsenic depend on the level of exposure and the length of time
the exposure occurs. An individual’s personal vulnerability will also affect susceptibility
in addition to the specific exposure circumstances.
Acute exposure to moderately high levels of arsenic (i.e., more than about 50 micrograms arsenic per kilogram body weight per day [50 µg/kg/day] for a few days or less) is usually characterized by vomiting, diarrhea, abdominal pain, and gastrointestinal bleeding; liver and kidney effects; changes in blood pressure and heart rate; fluid in the lungs and difficulty breathing. Arsenic exposure may also result in neurological effects, depending on the level and length of exposure. High doses (greater than 2,000 µg/kg) have resulted in encephalopathy, peripheral neuropathy, confusion, lethargy, seizures, and coma.

Although peripheral neuropathy has been reported following acute exposures, it is more typical of longer-term, lower-dose exposures (30-100 µg/kg/day for more than a few days). This neuropathy is described as numbness in hands and feet, progressing to painful “pins and needles” sensations. Sensory and motor neurons are affected. Patients often recover fully from less severe cases, but the effects are permanent in the most severe cases.

The staff does not expect that acute or chronic non-cancer toxicity will be a regular outcome of normal contact with CCA-treated wood play structures because the arsenic doses we have estimated are much lower than the doses that cause clinical effects. The staff acknowledges the cases of adverse health effects reported by parents and other consumers, but we believe that the unusual characteristics of the wood (e.g., covered with white residue, leaking colored liquid), or specific behaviors (e.g., ingestion of rainwater that collected on the surface of the structure) that were reportedly associated with adverse health effects in these specific cases are not typical of most CCA-treated wood products or of children and their playtime behaviors with CCA-treated wood play structures.

There have also been reports of non-workplace related acute toxicity in persons who have worked with CCA-treated wood in construction projects without using protective equipment (e.g., safety glasses, gloves, mask or respirator) or in individuals who have burned the wood. As stated in the staff briefing package, there are a number of exposure routes and mechanisms involving children’s contact with arsenic-containing residues from wood or nearby soil other than that specifically considered by the staff in its exposure and risk assessment. Any potential risks from additional exposures would add to the staff’s estimate of risk.

11) Mrs. Janak referenced a number of articles related to arsenic that were not listed among the references used by the staff in their assessment of the toxicity of arsenic. If relevant, have they been reviewed to see if they provide any additional information?

Response: The staff reviewed Mrs. Janak’s bibliography and obtained some of the referenced reports. These papers and the referenced papers provide similar information to the papers that the staff previously reviewed. None of these other papers provides any additional data, e.g., on dose and response, that would be useful in the staff’s risk assessment.
12) Does the upper end of our risk assessment cover groups who have higher rates of hand to mouth activity, and perhaps more years on playground equipment, such as Down syndrome children? Or would their risk of cancer likely be higher?

Response: The technical staff believes that the range of risks calculated in the staff’s assessment covers children who play on CCA-treated playground equipment with the most likely and reasonably foreseeable exposure conditions and behaviors.

The staff recognizes the immense variability among individuals, in both activities and behaviors, and in susceptibility to disease. Although some children are likely to be at greater risk than we have estimated, it is not possible to precisely estimate risk for all situations or for specific individuals. The risk to children with Down syndrome might fall within the staff’s estimated lifetime cancer risk range, or it could be higher or lower depending upon specific behaviors and exposure conditions. The staff cannot make a definitive conclusion about the risk to children with Down syndrome or to any other group of children. However, the staff recognizes that children with Down syndrome, as well as very young children, generally exhibit more mouthing behaviors than other children.

The staff estimated a lifetime cancer risk range of two to 100 per million for a person who played on CCA-treated playground equipment in early childhood. This estimate relied mostly on central tendency estimates for each variable (e.g., averages), although the unit cancer risk (the dose-response term) was represented by a range of values derived by two different bodies (EPA Office of Water, and the National Research Council subcommittee on arsenic in drinking water). The use of a range for the unit risk is responsible for the range of risk in the output. Thus, the resulting risk range is not based on a range of behaviors.

The staff also conducted a sensitivity analysis of its risk assessment, which resulted in a range of risks of 0.2 to 5,000 per million. The goal of the staff’s sensitivity analysis was to estimate reasonable “best” and “worst” cases of risk. The staff’s goal in this assessment was to capture a range of values for each of several parameters to represent extremes of behavior or vulnerability. For example, the staff estimated an average residue ingestion rate of about 43 percent of the daily handload. The staff estimated that at the extremes, children might ingest much less than this (about 3 percent), or much more (i.e., 700 percent, or about 16 times more than the average). The staff believes that this expanded risk range covers children who have even greater exposure and risk than the average children considered in the assessment. However, the staff’s assessment did not explore all risk factors or quantify combinations of extreme behaviors and personal risk factors.
13) Do we have any information to support Ms. Logomasini’s statement that Lowes and Home Depot went back to selling CCA-treated wood because of builder resistance to alternatives they were selling?

**Response:** Ms. Logomasini wrote\(^2\) that in her December 16, 2002 conversation with Kent Knutson, Vice President for Government Relations for Home Depot (Washington office), Mr. Knutson stated, without any explanation, that the company had problems selling the alternatives and went back to selling only CCA-treated wood. Ms. Logomasini also stated that Lowe’s and Home Depot continue to have problems selling CCA-treated wood and that alternatives are now only available by “special order” and are not being stocked in the stores as planned. She provided no additional information to support this statement.

Wood treated with the alternative chemicals costs as much as 20 percent more than CCA-treated wood. A spokesperson for Home Depot was quoted in the press\(^3\) as stating that in stores where both were available, the demand for the CCA-treated wood was greater. He attributed the greater demand to the price difference. A builder quoted in the same article also indicated that he was still offering CCA-treated wood because of the price difference and that most of his customers were not concerned about the arsenic issue. However, he also said that he was not concerned about the phase out of CCA-treated wood because it would increase the total price of decks or houses by only a small amount.

It might also be noted that a newspaper article\(^4\) provided to CPSC staff by Ms. Logomasini quotes a Lowe’s spokesperson as saying that the company moved into selling ACQ right away due to customer demand.

14) Does staff have the list of articles, papers, etc. that the Florida Physicians Arsenic Workgroup (FPAW) reviewed in reaching their conclusions on arsenic in pressure-treated wood and did staff review them as part of the preparation of the briefing package?

**Response:** CPSC staff has reviewed the report. All significant references had been reviewed by staff while preparing the original risk assessment. There was nothing new in either the report or its references that would cause staff to alter its conclusions.

The FPAW concluded that use of CCA-treated wood structures would not adversely affect the health of children or adults. This conclusion was drawn from two lines of evidence: 1) they found no reports of clinical disease related to arsenic exposure from contact with CCA-treated wood playground structures or surrounding soil, and 2) they believe that arsenic exposure from CCA-treated wood is insignificant compared to

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\(^2\) This information was provided in a letter dated June 12, 2003 to CPSC staff from Angela Logomasini, Competitive Enterprise Institute, in response to a staff inquiry.


background sources, based both on level of exposure, and characteristics of the arsenic exposure, i.e., bioaccessibility and bioavailability.

CPSC staff is not aware of any epidemiology study examining the relationship between adverse health effects and contact with CCA-treated wood structures or surrounding soil. Since the staff's estimate of average arsenic exposure from playing on CCA-treated wood playground equipment is approximately the same as the average arsenic intake from food and both will vary on a daily basis, it will be very difficult to correlate changes in exposure from CCA-treated wood playgrounds with health effects or arsenic levels in urine or hair. For this type of study to provide meaningful data, it would require a very robust study design, and would take years to design and conduct. The increased risk of lung or bladder cancer that CPSC staff identified would not be expected to be observed as a spike in clinical databases. Rather, it is an increase in cancer risk that would be difficult to detect over the relatively high rates of cancer in the U.S. from other causes. CPSC staff has received reports of illness that consumers have associated with exposure to CCA-treated wood structures. Although the staff acknowledges that the adverse effects in these reports have not necessarily been proven to be linked to the CCA-treated wood, we do not believe that the lack of well-documented clinical reports of CCA-treated wood-related illness is proof that adverse outcomes are not possible.

Concerning the second point made by the FPAW, the staff is not aware of any peer-reviewed study on the bioavailability of arsenic from CCA-treated wood, much less one that suggests that bioavailability is insignificant. On the contrary, the FPAW report (p.2) notes that "...Human studies show that absorption of inorganic arsenic via the gastrointestinal tract is rapid and virtually complete." The conclusions of the FPAW rely upon the assumption of low bioavailability without providing data to support this assumption. In addition, the appendix in the FPAW report on arsenic bioavailability refers to bioavailability in soil. CPSC staff did not consider exposure to arsenic from children playing in soil near playground structures when assessing risk.

15) Please provide us with a copy of the risk assessment the European Union did on CCA-treated wood.

Response: A copy of the European Union risk assessment has been provided to the Commissioners. This document is copyrighted and, therefore, will not be attached or made available to the public through CPSC.
Staff Response to Written Public Comments

I. General Issues

There are several general issues that were discussed in the written public comments by many submitters. The names and affiliations of the submitters are found in Appendix B. Most general comments discussed the rationale to grant, deny, or defer action on the petition. There was also a comment that the "precautionary principle" should be employed by the Commission when making a decision.

A. Grant Petition to Ban CCA-Treated Wood Playground Equipment and/or Recall Playground Equipment

Comments were received from many consumers and an environmental health web site publisher stating that CCA-treated wood or CCA-treated wood playground equipment should be banned from the marketplace and/or recalled from consumer use as it poses a hazard to the health of consumers.

Comment: Several consumers (Gloria Tilley; Sherrie Maykut; Colleen Murphy) commented that their children were poisoned by the use of CCA-treated wood structures and urged the Commission to grant the petition. One consumer (Ms. Maykut) requested that CCA-treated wood be banned from use in playgrounds and that existing structures be recalled. Many other consumers wrote that they were concerned about the lack of immediate action without regard to CCA phase-out under EPA in conjunction with the CCA manufacturers; they are concerned that this will allow these products to remain on the market.

Response: CPSC staff performed a quantitative risk assessment for a person using CCA-treated wood playground equipment and found that a person who plays on CCA-treated wood playground structures during early childhood has an increased risk of lung or bladder cancer over his/her lifetime. Staff believes that the remedy sought by the petitioners, i.e., to have CCA-treated wood playground equipment removed from retail sale, has essentially occurred. The major manufacturers of wood playground equipment have informed CPSC staff that they no longer use CCA-treated wood to manufacture this equipment. Furthermore, EPA recently finalized the cancellation of the CCA pesticide registration and CCA will no longer be available to treat wood for most consumer uses, including use in playground equipment, after the end of 2003. This cancellation, which was requested by the CCA manufacturers, ensures that CCA cannot be used to treat wood for most residential uses under penalty of law under FIFRA. Although CCA-treated lumber is expected to be sold for several months past this date, it is expected that most of the CCA-treated wood will be out of the retail stream by June 2004.

CPSC and EPA staff are currently working to identify stains and sealants that can be used on CCA-treated wood structures to minimize the amount of arsenic leaching from the wood. Identification of such stains and sealants would provide an option for consumers who wish to reduce potential exposure to arsenic from CCA-treated wood structures.
To initiate a recall of CCA-treated wood playground equipment, the Commission would first have to determine that such structures are a hazardous substance defined by the Federal Hazardous Substances Act (FHSA). That is, the products would have to be toxic and may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable ingestion by children. If a child’s product is a hazardous substance or bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted, it is automatically banned under section 2(q)(1)(A) of the FHSA. To compel a recall of such a product, the Commission would have to show, after a hearing, that a recall is in the public interest.

If a child’s product were not a banned hazardous substance and the Commission wished to pursue a recall, we would have to establish that the product contains a defect that creates a substantial risk of injury to children because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, and that notification and remedial action is in the public interest.

Comment: Larry Frame and approximately sixty other consumers commented that while they were pleased that Commission staff validated the existence of a health risk from the use of CCA-treated wood playground equipment, they were disappointed that picnic tables and decks were not evaluated for similar risks to children. Theodora Briggs Sweeney, a consumer, noted that the CPSC staff recommendation that children wash their hands after playing on CCA-treated wood playground equipment was inadequate because children put their hands in their mouths before they can get them washed. Another consumer, Enid Narver, commented that chemists need to find a “neutralizer” for CCA-treated wood. Joseph Prager, publisher of www.bancca.org, an environmental health web site, noted that CPSC staff should have provided information on mitigation.

Response: Picnic tables, decks, and other structures were not evaluated by CPSC staff because the part of the petition that was docketed did not request action on these products. While the staff risk assessment was based on exposure to arsenic from CCA-treated wood playsets, staff acknowledged that risks related to exposures from other wood sources and the soil surrounding these structures would be in addition to those from CCA-treated wood playsets. Therefore, the overall risk to children from playing on or near CCA-treated wood structures is likely to be higher than that estimated in the staff analysis.

CPSC staff acknowledges that children sometimes put their hands in their mouths after playing, before they can get them washed. However, hand washing is a very effective means to reduce children’s risk to arsenic exposure from CCA-treated wood, since the primary route of exposure for children is believed to be via the mouth when young children put their hands or other objects that they have touched and contaminated into their mouths.

It is unclear what the commenter means by a “neutralizer” for arsenic in CCA-treated wood. The wood is impregnated with CCA. Staff is working with EPA to determine whether there are stains and sealants that can be used to decrease the amount of dislodgeable arsenic on the surface of the wood.
B. Deny Petition to Ban CCA-Treated Wood Playground Equipment and/or No Recall of Playground Equipment

Several individuals or organizations commented that CCA-treated wood should be kept on the market, as it does not pose a hazard to consumers.

*Risk Overstated*

**Comment:** Tim McMahon, consumer, does not believe that CPSC should ban the use of CCA in playground equipment because EPA has grossly overstated the potential carcinogenic effects of CCA in playground equipment. Both Woods Run Forest Products, Inc., a wood treatment company that uses CCA, and the American Forest and Paper Association (AFPA) do not believe CCA-treated lumber should be banned, since neither the EPA nor the Florida Physicians Arsenic Workgroup concluded that CCA-treated wood poses unreasonable health risks to the public.

**Response:** CPSC staff performed a quantitative risk assessment for a person who plays on CCA-treated wood playground equipment during early childhood and found an increased risk of developing lung or bladder cancer to a child over his/her lifetime from using this equipment. The risk finding is not in conflict with the conclusions of EPA or the Florida Physicians Arsenic Workgroup because neither one of these groups has performed a quantitative risk assessment to date. EPA has not yet reached a conclusion regarding carcinogenicity or other health effects of CCA-treated wood. EPA’s risk assessment is expected to be completed and presented to the EPA Science Advisory Panel in late fall 2003. Preliminary data from industry’s hand wipe study of CCA-treated wood shows comparable levels of dislodgeable arsenic to those found in the CPSC staff’s study (Gutknecht et al., 2003). The Florida Physicians Arsenic Workgroup reviewed the scientific literature on arsenic and wrote a report, but did not perform a quantitative risk assessment. They concluded that there is no risk based on the apparent lack of data on the incidence of clinical disease associated with the use of playground equipment and contaminated soil. The increased risk of lung or bladder cancer that CPSC staff identified would not be expected to be observed as a spike in clinical databases. Rather, it is an increase in cancer risk that would be difficult to detect over the relatively high rates of cancer in the U.S. from other causes. The conclusions of the Florida Physicians Arsenic Workgroup also rely upon the assumption of low bioavailability without providing data to support this assumption.

*Questionable Science*

**Comment:** Wood Run Forest Products, Inc. states that banning CCA has no basis in science. Capital Research Center (CRC) commented that the human health risk based on exposure to CCA-treated wood is “unsettled” and that the Commission should consider several issues when making a decision. The Wood Preservative Science Council, Inc. (WPSC), which represents the scientific views of the CCA chemical manufacturers, notes that the petition should be denied because the science does not show that there is any “meaningful” risk from the use of CCA-treated wood playground equipment. Further, WPSC believes that CPSC staff has found only theoretical risk and that data obtained from studies currently being performed by WPSC will assist EPA in its risk assessment.
S.I. Storey Lumber Company, Inc. recommended that the petition be either denied or deferred. Storey Lumber noted that if the CPSC were to grant the petition based on the staff’s finding in the risk assessment and subsequent scientific work refuted these findings, then the reputation of the agency would be at stake.

Response: CPSC staff believes that its risk assessment is based on sound science and the best data provided to or obtained by the staff. CPSC staff performed a quantitative assessment of cancer risk to a child who uses CCA-treated wood playground equipment and found an increased risk of developing lung or bladder cancer to that child over his/her lifetime. The risk was calculated based on the staff’s analysis of published scientific data and data from studies performed by CPSC staff, who examined the amount of dislodgeable arsenic that was removed from in-use CCA-treated wood playground equipment and decks. Thus, the exposure data in the risk assessment was not theoretical, but represents actual experimental results. The deterministic risk assessment used by staff involved a standard approach that is used to assess many types of risks. The approach used has been adapted for exposure scenarios that are relevant to the use of playground equipment. This approach is similar to the risk assessment approaches used by other groups.

Economic Impact

Comment: The Small Business Survival Committee (SBS), a nonprofit small business advocacy organization, commented that the Commission should deny or delay a ban on CCA-treated wood playground equipment until the Commission can fully understand the impact to small businesses. They urge the Commission to delay action until the science and the economic impact of a ban has been evaluated. They further assert that it is unknown whether consumers will ever accept alternatives because they do not afford the same level of efficacy against degradation by water and insects as CCA.

Capital Research Center, Inc. (CRC) notes that a ban on CCA-treated wood products will raise the cost of wood structures, such as decks, and will place an economic hardship on lower-income families. They note that a major retailer tested wood treated with CCA alternatives in stores and found that it did not sell as well as CCA-treated wood. The AFPA asserts that the ban should not be implemented because there may be market disruption to the non-arsenical preservative market, which is an $8 billion/year industry. The National Labor Management Committee (LMC) of the Forest Products Industry, Western Region United Brotherhood of Carpenters and Joiners of America, put this figure at $40 billion. The LMC is concerned about possible job loss of its members due to market disruption.

Response: The EPA has cancelled the pesticide registration for CCA, therefore, it will no longer be manufactured for use in treating wood for most consumer uses at the end of 2003. This action was requested by the registrants. There is no action that the Commission can take that would require or allow the use of CCA for treating wood for these purposes. Thus, small businesses that pressure treat wood will not be affected by any action on the petition by the Commission. Any expense to small businesses resulting from the need to convert their facilities for the use of ACQ or other chemical alternatives is predicated by the voluntary registration withdrawal request by industry and the subsequent CCA cancellation by EPA.
There is likely to be an increase in the price of pressure-treated wood as CCA is being replaced by more expensive alternative treatments. However, this is irrespective of any action on the part of the Commission because of the cancellation of the CCA registration. CCA-treated wood will no longer be manufactured for essentially all consumer uses after the end of 2003, and alternative chemicals will be used in its place. Staff believes that there are insufficient data to predict whether consumers will “accept” the alternatives to CCA, but acknowledges that cost and efficacy might be factors that affect consumer choices. No evidence was provided to CPSC staff that there would be a potential for disruption to the non-arsenical preserved wood market if a ban on CCA-treated wood was implemented.

The outcome of the petition process is unlikely to affect the status of the manufacture of CCA-treated wood playground equipment for several reasons. Most major manufacturers of wood playground equipment have informed CPSC staff that they have already stopped using CCA-treated wood to make their products. Some have switched to using pressure-treated wood made using ACQ or another alternative to CCA. Other manufacturers switched to the use of redwood or cedar.

Alternatives to CCA

Comment: Both the SBS and Wood Run Forest Products are concerned that the CCA alternatives, such as ACQ, have not been adequately tested for health and ecological effects. Tim McMahon, a consumer, states that the alternatives to CCA are inferior, as hardware corrodes when in contact with it.

Response: Insufficient data exist on the toxicity and exposure to the chemical alternatives to CCA to make a decision regarding the risk to individuals exposed to wood treated with these products. The toxicity of alternative chemicals to CCA will be reviewed by EPA under its statutes. CPSC staff understands that some types of metal hardware corrode when in contact with certain alternative-treated wood. However, staff has been told by the wood treaters that stainless steel hardware will not corrode when in contact with the wood, and that this type of hardware is recommended for use with ACQ-treated wood.

Voluntary Withdrawal

Comment: At the March 18, 2003 public hearing, Chairman Stratton asked whether a ban would make any difference to the industry, since CCA is already being voluntarily withdrawn from the market. In response to this question, the LMC and the AFPA noted that since CCA registrants have already voluntarily agreed to terminate most consumer uses of CCA-treated wood, there is simply no need for CPSC to act to ban. They note that this is because the petitioners have already received the remedy that they sought and further action would not be in the interest of “good government.” They stated that the reason for the voluntary withdrawal of the CCA registration is because manufacturers wish to respond to market demand for a product that does not contain arsenic and not because such use poses a risk to human health. The Wood Preservative Science Council (WPSC) commented that the Commission should deny the petition because CCA-treated wood is no longer used to manufacture playground equipment since CCA has been withdrawn in a legally enforceable manner for certain uses, including use in playground equipment. They note that a voluntary transition to
alternative treatments has already begun. Thus, the relief sought by the petition has been effectuated.

**Response:** EPA recently finalized the cancellation for the registration of the pesticide CCA. As a result, CCA will no longer be available to treat wood for most consumer uses, including use in playground equipment, after the end of 2003.

**Comment:** Woods Run Forest Products, Inc. suggests that CCA manufacturers have "volunteered to ban" CCA to boost sales of their products that have not competed well in the past with CCA or to try to distance themselves from a public misperception about arsenic in the CCA. Capital Research Center (CRC) stated that nonprofit advocacy groups that petitioned CPSC, such as the EWG, are notorious for using scare tactics and urged the Commission to be judicious when trying to understand their goals and motivations.

CRC also noted that inner city children would lose recreational opportunities if the ban were implemented. Storey Lumber Company noted that granting the petition would cause undue public alarm, resulting in less physical activity among children, which might lead to Type 2 diabetes, which would be a greater harm than the use of CCA-treated playground equipment.

**Response:** The EPA has cancelled the pesticide registration of the chemical CCA for pressure treating wood for most consumer uses. This cancellation, which was requested by the CCA manufacturers, ensures that CCA cannot be manufactured for these uses under penalty of law under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

There were no data provided to support the contention that inner city children would lose recreational opportunities if the ban were implemented or that alternatives to CCA-treated wood would not sell as well as CCA-treated wood itself. Also, no data are available to show that granting the petition would result in less physical activity for children.

**C. Defer Petition to Ban CCA-Treated Wood Playground Equipment**

Four commenters recommended that the Commission defer action on the petition. The comments of one of these, Storey Lumber, which recommended denial or deferral of the petition, are abstracted under the "Deny Petition" section above.

**Comment:** The AFPA believes that CPSC should not act to address the petition until the EPA studies on surface and soil residue bioavailability, and a hand wipe study, are completed and until a joint CPSC-EPA study on mitigation is completed.

**Response:** The EPA has not yet completed its risk assessment regarding the risk of cancer or any other health effects from the use of CCA-treated wood. This risk assessment is expected to be completed and presented to the EPA Science Advisory Panel in late fall 2003. A preliminary abstract of data from an industry-sponsored study of dislodgeable arsenic levels in CCA-treated wood indicated that they are similar to the levels found in the CPSC staff studies (Gutknecht et al., 2003 [abstract]). Preliminary data from another industry-sponsored study using juvenile swine indicate that the bioavailability of dislodgeable arsenic residue from CCA-treated wood after oral dosing,
while different from the default value used by the staff, is within the range of bioavailability values applied in the CPSC staff sensitivity analysis (Casteel et al., 2003 [abstract]).

CPSC staff has conducted its own risk assessment for Commission consideration. The CPSC risk assessment is based on staff studies as well as published scientific data. Although the CPSC-EPA mitigation study is currently being conducted, the Commission can choose to determine the disposition of the petition without data from this study.

**Comment:** The National Association of Home Builders (NAHB), a federation of state and local homebuilder associations, and Consumer Alert recommend that the Commission defer action on the petition pending final action by the EPA to cancel the pesticide registration of CCA. NAHB believes that only high quality information based on sound science should be used by CPSC when determining health risks associated with CCA-treated wood and is concerned that use of unfounded or inaccurate information can cause unintended concerns leading to recall of existing in-use CCA-treated lumber.

**Response:** EPA has cancelled the pesticide registration of the chemical CCA for pressure treating wood for most consumer uses. This cancellation, which was requested by the CCA manufacturers, ensures that CCA cannot be manufactured for these uses under penalty of law under FIFRA. The staff employed sound scientific practices and used or obtained the best available data in conducting its risk assessment. The risk assessment was subjected to internal and external scientific peer review and all comments were considered and addressed as appropriate.

**Comment:** Consumer Alert commented that the Commission should defer the petition pending expected action by EPA to complete an industry agreement to phase-out sale of CCA-treated wood. They note that CPSC used EPA research to assess the risk from CCA-treated wood. They also state that CPSC has always had problems dealing with chronic hazards because CPSC is not well equipped to deal with such hazards, even though the agency has jurisdiction for them under the Federal Hazardous Substances Act (FHS). While Consumer Alert agrees with the CPSC staff that the petition be deferred until EPA action is finalized, they are concerned that municipalities will be pressured into removing existing equipment, in which case, children might have to play in the streets.

**Response:** The proposed action on CCA-treated wood was finalized by EPA in early 2003. Thus, EPA has taken its final action with regard to the production and sale of the chemical CCA to be used for treatment of wood for most consumer uses, including use in the manufacture of playground equipment.

CPSC has been investigating chronic hazards since its inception and regularly undertakes work on chronic hazards, as noted by its most recent work on a petition to ban certain children's products containing phthalates and its work to stop the use of lead as a stabilizer in imported vinyl miniblinds.

Contrary to the assertions of Consumer Alert, CPSC staff did not use EPA research results in its risk assessment. CPSC staff performed a quantitative risk assessment on the carcinogenic effects of exposure to arsenic for people who had contact with CCA-
treated wood playground equipment in childhood, based in part on data from scientific studies conducted by CPSC staff. Although EPA is currently working with the American Chemistry Council (ACC) on its studies, preliminary data from ACC studies of dislodgeable arsenic levels do not differ significantly from the results of the CPSC staff’s scientific studies and preliminary data from the bioavailability study indicate that while bioavailability in swine might be different from the default value used by the CPSC staff in its risk assessment, it is within the range of bioavailability values applied in the CPSC staff sensitivity analysis (Casteel et al., 2003 [abstract]).

D. Precautionary Principle

Comment: Merrill Clark, a consumer, states that the “precautionary principle” appears to be defunct or is not considered in regulatory affairs, and believes that toxic-releasing wood should not be allowed into the market in the first place.

Response: The "precautionary principle" generally involves a conservative response to a perceived risk where objective data are not sufficient to confirm that there is a problem. The CPSC must follow the statutory requirement of the Federal Hazardous Substances Act (FHSA) that a hazardous substance determination be based on a finding that the substance is toxic, corrosive, flammable, combustible, an irritant, a strong sensitizer, or generates pressure through decomposition, heat, or other means, and that it may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children. Furthermore, the FHSA requires that finding to be supported by substantial evidence on the record.

E. CPSC Must Adhere to Data Quality Guidelines

Two organizations submitted comments on issues relating to the Office of Management and Budget (OMB) Data Quality Guidelines.

Comment: The National Association of Home Builders (NAHB), and the Competitive Enterprise Institute (CEI) asserted that the information disseminated by CPSC concerning CCA is subject to federal Information Quality Guidelines, issued on February 22, 2002 by OMB (67 FR 5482).

Response: Based on the content of the comments, it appears that the submitters were requesting that the Administrative Correction Mechanism of the CPSC’s Information Quality Guidelines be invoked with respect to the staff briefing package. As stated on page 9 of the CPSC Guidelines, the Administrative Correction Mechanism is not available for information disseminated by the CPSC through a comprehensive public review process, such as the staff briefing package and a public meeting. The briefing package was the subject of an extensive public comment period, as announced in the Federal Register. The public meeting was held on March 17-18, 2003.

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II. Specific Issues

There are several specific issues that were discussed in the written public comments. Most specific comments discussed the CPSC staff exposure studies and risk assessment, comparative risk to arsenic from sources other than CCA-treated wood, and economic issues that the Commission should consider when making a decision on the petition.

A. CPSC Staff’s Exposure Studies and Risk Assessment

Two submitters commented on the design of the CPSC staff’s exposure studies.

**Comment:** Joseph Prager, publisher of the bancca.org web site and Barbara Beck of Gradient Corporation (on behalf of the Wood Preservative Science Council) suggested that the total number of decks and playsets sampled in the CPSC investigation was too small, and all of the structures sampled were in the Washington, D.C. metropolitan area.

**Response:** CPSC staff’s studies looked at 20 decks/playgrounds in the Washington, D.C. area, which is the most extensive peer-reviewed study staff is aware of to date. While the total number of samples may appear small, the results are consistent with other similar published studies. The levels of dislodgeable arsenic from CCA-treated wood in the staff’s study were compared to data from published investigations conducted in other regions of the United States and Canada (Thomas, 2003). These studies used both hand and surrogate data, with wide variations in results. However, the ranges of dislodgeable arsenic found in these studies, as well as preliminary data from an industry-sponsored study (Gutknecht et al., 2003) are comparable to those found in the CPSC staff’s study. One study that sampled 10 playsets with a cloth surrogate in Ontario, Canada reported a range of values that were remarkably similar to those in the CPSC staff’s studies. These results suggest that although there may be regional differences in dislodgeable arsenic, the overall results are expected to be similar.

A large portion of the U.S. population (e.g., NY, PA, NJ) experiences climatic conditions similar to those found in the Washington, D.C. area. If weather conditions are a factor in arsenic migration from wood, it is reasonable to assume that exposure studies performed in these areas would produce results that are similar to those found in the Washington D.C. area. If a risk exists for children living in these locales, it represents an elevated risk for a substantial portion of the U.S. population.

**Comment:** Joseph Prager, publisher of the bancca.org web site, noted that 50% of the decks tested in the CPSC study had some type of sealant, stain, or finish, and that, of the 12 playsets sampled by CPSC staff, 5 had been treated, another 5 were listed as unknown, and 2 were untreated. He suggested that treating the wood with a stain or sealant may lower the amount of arsenic in the wipe tests, and that, therefore, the significant number of treated structures used in the study may have skewed the results to a lower value than would be obtained from non-treated structures. Mr. Prager also remarked that the retention levels of CCA (arsenic) in the wood used in the study were not provided.

**Response:** Decks and playsets in current use across the U.S. vary widely in their age, surface coatings, and use patterns. CPSC staff used a convenience sample of in-use
decks and playsets that reflected this variety of age and coatings. CPSC staff believes that the mean value of arsenic transfer derived from the sampling provides a reasonable estimation of the potential arsenic exposure from CCA-treated structures over a variety of ages and finishes.

CPSC staff did obtain wood labels for a number of structures in the study. All of the labels indicated that the wood had been CCA-treated at 0.4 pounds per cubic foot. It is known that the vast majority of residential CCA wood lumber is treated to this retention level.

CPSC staff also collected core samples from each of the decks and playsets, analyzed them for arsenic and used these data to compare the relative percentage of the arsenic in the core wood and in the CCA transferred to hands. However, there are many factors that impact arsenic migration from wood (e.g., pressure applied, treatment, age, etc.), not just the relative percentage of each metal in the core wood.

**Comment:** Under the FIFRA, EPA is currently conducting human and ecological risk assessments relating to CCA-treated wood. Although the focus of its assessments is much broader than that of CPSC, EPA is considering children’s contact with CCA-treated wood playground equipment. EPA is using probabilistic techniques for this part of its review. One commenter (Gradient Corp., on behalf of the Wood Preservative Science Council) stated that the CPSC staff’s use of a deterministic model is appropriate.

**Response:** Please refer to the staff’s response to Question 2, posed by Commissioner Moore.

**Comment:** Several commenters objected to the staff’s exposure estimates, which relied on calculation of the lifetime average daily dose (Wendy Gramm and Susan Dudley, on behalf of the Mercatus Center; Steven Lamm/Michael Kruse, on behalf of the Wood Preservative Science Council; Kenneth Brown and Angela Logomasini, on behalf of the CEI; Jody Clarke of the CEI).

**Response:** The lifetime average daily dose, or LADD, is the sum of all the daily exposures that occur during the lifetime divided by the number of days in an average lifetime. The LADD is “the most common dose metric used in carcinogen risk assessment” (Paustenbach, 2002). Furthermore, the use of the LADD is standard practice even when exposure does not occur over the entire lifetime. The theory is that the doses in short-term or intermittent exposures can be prorated over the lifetime to get the equivalent daily dose, as if a lower exposure had occurred over the lifetime.

Among risk assessors, increasing attention is being paid to issues around assessing risks from short-term or intermittent exposure, especially short-term exposures that occur during childhood (EPA, 2003; Ginsberg, 2003). Ginsberg reviewed more than two dozen studies in mice and rats concerning the tumorigenicity of several different chemicals. His analysis shows that short-term exposures in early life can lead to lifetime carcinogenic responses that equal or exceed the responses in adults exposed for much longer periods of time. Ginsberg suggests that early life exposures should not be prorated over the lifetime (i.e., calculation of LADD), and that instead the cancer risks for different life stage exposures should be calculated separately, using the same
adult-based cancer slope factor, and then added. For an exposure that occurs only during childhood, this procedure would result in a much higher estimate of lifetime risk than the standard method.

In the current CPSC staff assessment, the quantitative assessment of risk from exposure to arsenic is based on populations with lifetime exposures to arsenic through drinking water and food. Thus, the effects from exposure in early life are inherent in the analysis, and the specific effects of early life or adult exposures cannot be determined. Because the staff estimated cancer risk from quantitative analyses based on lifetime exposures and not just on adult exposure, the staff does not believe Ginsberg's model should be applied to this case.

Similarly, a recently released draft guidance by an EPA scientific panel (EPA, 2003) advises that agency cancer risk assessments for childhood exposure should consider the mode of action, and provides guidelines for quantitative adjustments to risk estimates. The panel wrote that for chemicals with a mutagenic mode of action, EPA should use linear extrapolation to lower doses and include a 3-fold or 10-fold adjustment to the cancer slope factor for early life exposures. Because of the lack of available data, the panel wrote that no adjustment is recommended if a mode of action other than mutagenicity is established, but that available data should be used on a case-by-case basis. Finally, if the mode of action has not been established, no general adjustment is recommended, although the recommendation for linear extrapolation to lower doses still stands. This is the case with arsenic.

The staff agrees that the LADD may underestimate or overestimate the cancer risk from exposure to arsenic, but given that the data are not sufficient to either identify the mode of action of arsenic or characterize the relative importance of early life exposures, the staff believes that this standard quantitative risk assessment approach is currently the best approach.

Comment: At least two commenters (Kenneth Brown, CEI; Jody Clarke, CEI) suggested that arsenic exposure in childhood would not result in increased lifetime risk of cancer, and used the example of smoking cigarettes. These commenters argued that because the risk of cancer decreases in people who quit smoking, the risk from exposure to CCA-treated wood playground structures would also decrease since exposure ends in childhood.

Response: As discussed elsewhere in this document (see Ginsberg, 2003), there is an increasing body of knowledge indicating that early life exposures can lead to lifetime carcinogenic responses that equal or exceed the responses in adults exposed for much longer periods of time. However, this type of information is not currently available for arsenic.

The data show that the cancer risk from cigarette smoking is related to a number of factors, including duration of exposure, age, time since cessation, and the amount of tobacco or number of cigarettes smoked (HHS, 1990). While it appears that smokers who quit smoking experience a reduced risk of cancer compared to people who continue to smoke, cancer risk remains significantly elevated in former smokers compared to those that never smoked up to 30 years after cessation (Ebbert et al., 2003).
Furthermore, unlike cigarette smoking, where exposure will be eliminated or greatly decreased upon smoking cessation, arsenic is ubiquitous in our environment and all individuals will have exposure throughout their lives, primarily through food and drinking water, in addition to the exposure from contact with CCA-treated wood playground structures during childhood. Thus, the level of arsenic exposure may change through one’s lifetime, but exposure will likely never end.

Therefore, the staff believes that the standard approaches to risk assessment, which assume that early life exposures contribute to the lifetime risk of cancer, are appropriate.

**Comment:** Several commenters (Wendy Gramm and Susan Dudley of the Mercatus Center; Gary Williams, Steven Lamm, and Michael Kruse, on behalf of the Wood Preservative Science Council) objected to the staff’s method of estimating arsenic ingestion after contact with CCA-treated wood structures. They favored conducting tests to determine the levels of arsenic in the urine or hair of children who have access to CCA-treated wood playground structures. One commenter (Gradient, on behalf of the Wood Preservative Science Council) agreed with the staff’s method for estimating hand-to-mouth transfer of arsenic-containing residues.

**Response:** Please refer to the staff’s response to Question 9, posed by Commissioner Moore.

**Comment:** One commenter (Gradient, on behalf of the Wood Preservative Science Council) stated that the staff overestimated exposure by not adjusting the exposure estimate to reflect the fraction of the day that children spend on the playground and to account for decreasing handload concentrations over time after the children leave the playground.

**Response:** The staff’s approach to calculating exposure to arsenic-containing residues used data on soil ingestion and soil hand-loading in children. Factors such as the fraction of the day the children spend on a playground, the amount of hand-to-mouth behavior exhibited, and decreasing handload with time are inherent in the staff’s analysis using soil ingestion and soil hand-loading data.

The staff used data on total daily ingestion of soil, which is assumed to result primarily from hand-to-mouth transfers. The ingestion is due to various unmeasured activities, such as swallowing dirt after placing fingers directly into the mouth or eating with hands without first washing. Then the staff considered the amount of soil that adheres to the skin of the hands. The data on soil hand-loading were derived from several studies that used various protocols to collect samples at one point in time during the day after children engaged in normal activities indoors, outdoors, or a combination of indoors and outdoors. These data were not adjusted for any factor related to location or activity, even though certain activities would be expected to effect the amount of soil on the hands and the amount of soil that ended up in the mouth. Thus, since the staff assumed that these soil data are directly analogous to the exposure of interest, no adjustment is required.

It should be noted that although the staff used data on soil ingestion to estimate the amount of arsenic-containing residues that would be ingested from contact with CCA-
treated wood, the staff did not estimate the amount of arsenic that would be ingested through contact with contaminated soil near CCA-treated wood structures. Any additional risk from the ingestion of arsenic-contaminated soil would increase the risk already calculated in the staff risk assessment.

**Comment:** A number of commenters (Wendy Gramm and Susan Dudley of the Mercatus Center; Jim Hale and Seth Goldberg, Gradient Corp., Gary Williams, Steven Lamm, and Michael Kruse, on behalf of the Wood Preservative Science Council; Sharon Kneiss of the American Forest and Paper Association; and David Crowe of the National Association of Home Builders) discussed the bioavailability of arsenic from CCA-treated wood residues. Commenters disagreed with the staff’s use of the default value (100 percent relative bioavailability), and discussed available data that they believe are relevant for assigning a value of less than 100 percent. Commenters also stated that data is currently being collected as part of a series of studies by the industry in coordination with EPA, and that the staff should wait for those data before completing the risk assessment or finalizing recommendations.

**Response:** Bioavailability is the term used to indicate the extent to which a substance is absorbed by the body. The CPSC staff knows of no published human or animal studies of bioavailability of arsenic from surface residue of CCA-treated wood, although the staff has reviewed a few studies that measured the bioavailability of arsenic in experimental animals dosed with CCA-treated wood sawdust or with arsenic-contaminated soil (Hatlelid, 2003a). These studies have shown that the bioavailability of arsenic from sawdust or soil relative to arsenic in water is quite variable, ranging from about 0 to 98 percent. Most results were less than about 50 percent.

There are, however, at least two reasons that these studies are not directly applicable to the determination of the bioavailability of arsenic from wood surface residues. The first issue is that the physical and chemical characteristics of the arsenic in the sawdust and soil may not be similar enough to the arsenic found in the wood surface residue for these studies to be relevant. The second issue concerns the conditions of the tests used to assess bioavailability. The laboratory experiments generally used relatively high doses of arsenic-containing soils or sawdust, which may not reasonably simulate the low-dose, repeated exposures that we would anticipate for children who contact the surface of CCA-treated wood structures. The staff believes that the available data are not adequate to address the bioavailability of arsenic from CCA-treated wood surface residues.

An EPA Scientific Advisory Panel (SAP) (SAP, 2001) also considered the available data and noted the deficiencies: 1) limited data on bioavailability of arsenic from soils, and 2) the lack of data about arsenic-containing surface residues. The SAP recommended that 100 percent relative bioavailability be used in risk assessment until appropriate research is conducted. Therefore, the staff used the default assumption of 100 percent (CPSC, 1992) for the relative bioavailability of arsenic from ingestion of arsenic-containing surface residue.

In this case, a relative bioavailability of 100 percent means that the bioavailability of arsenic from the wood surface residue is assumed to be the same as from the drinking water in the epidemiological studies. It does not mean that the arsenic from either the
wood surface residue or the drinking water is assumed to be completely absorbed into the body. Rather, it means that we assume that arsenic from the wood surface residues is absorbed to the same extent as arsenic from the drinking water sources in the epidemiological studies.

One of the studies currently being conducted by the industry concerns the bioavailability of arsenic from wood surface residues (discussed previously). While this information will help in our understanding of the characteristics of the residues, one study in animals, by itself, will not provide enough information to extrapolate to humans or to replace the default value.

**Comment:** The comments of Wendy Gramm and Susan Dudley of the Mercatus Center included a critique of the staff’s use of the mean, rather than the median, to describe the results of sampling CCA-treated wood structures for the amount of arsenic that collects on hands from contact with the wood surface. They point out that the mean of a non-symmetrical dataset (e.g., one that contains some values that are much higher than the rest of the values) is higher than the median. The commenters refer to points at the end of the distribution as “outliers.” However, they wrote that if the distribution of data points is representative of the population, the mean could be the best choice. They claim that because of the small sample size, the shape of the population distribution is unknown, and therefore, the mean should not be used in this case because it gives disproportionate weight to the “outliers.”

**Response:** The staff agrees that the mean is about twice the value of the median, but disputes the commenters’ characterization of the data. The study of deck and playground equipment conducted by the CPSC staff is one of the largest exposure studies of its kind to date. Furthermore, the results from the deck and playground equipment sampling are consistent with data collected previously by CPSC staff and other investigators (discussed in Thomas, 2003), which also show log-normal or skewed distributions. Consequently, the staff believes that a non-symmetrical population distribution is supported by the available data. Therefore, the staff believes that the use of the mean is appropriate and that the effect of using the mean is to incorporate data points at the upper end of the distribution into a single number that represents all the observed data.

**Comment:** David Crowe, on behalf of the National Association of Home Builders stated that the staff assumed an exposure frequency (i.e., playground visits) of 156 times per year, and that this estimates seems like an “extraordinarily high number.” He suggested that a survey be conducted to ascertain the actual figure.

**Response:** The staff chose to focus on estimating the risk for a person who plays on CCA-treated wood playground structures during early childhood. The value used in the risk assessment was determined by CPSC staff from information in the published scientific literature, including a study that specifically determined the frequency of playground visits and data on children’s attendance at school or preschool (Midgett, 2003). The staff does not agree that an additional survey is needed. The staff chose 156 days of playground visits per year (3 days per week) as the central estimate for active children in a temperate climate, but acknowledged the large variation in average playground visitation rates in different geographical regions, with a range of 104 visits...
per year (2 days per week) to 230 visits per year (4.4 days per week). The uncertainty analysis takes into account how the variation in numbers of playground visitations per year would affect the risk.

**Comment:** Two commenters, Joseph Prager, publisher of the bancca.org web site, and Gloria Tilley, a consumer, raised the possibility of special populations of children that would be more at risk than the "average" population considered by the staff. Gradient Corp. (on behalf of the Wood Preservative Science Council) discussed several similar points raised by commenters at the March 17-18, 2003 public hearing, specifically comments related to children with Down syndrome and the possible reasons that this vulnerable population could be especially susceptible to the effects of arsenic exposure (Janak, 2003). Gradient's comments discuss the theoretical basis for increased susceptibility for children affected by Down syndrome, but note that no data links arsenic exposure to illnesses associated with Down syndrome, including leukemia. Gradient also criticized the parameter values used in the staff's sensitivity analysis as being unlikely, particularly for the hand-to-mouth transfer term. In addition, Gradient criticized the high end of the unit risk range the staff used to calculate risk in both the main risk assessment and the sensitivity analysis. Thus, they believe that the combination of these two extreme input values results in very high, and implausible risk estimates, even for sensitive populations.

**Response:** Please refer to the staff's response to Question 12, posed by Commissioner Moore, for the staff's discussion of issues related to vulnerable populations.

As discussed elsewhere in this document, the staff believes that the high end of the unit risk range, derived from the quantitative analysis of the National Research Council (NRC, 2001) is a reasonable estimate of the upper end of the unit risk range, although it is subject to uncertainty based on the limitations of the epidemiological data and statistical modeling.

**Comment:** A number of consumers have described acute or chronic non-cancer toxicity that reportedly occurred after exposure to arsenic in CCA-treated wood or could potentially result from contact with CCA-treated wood (Joseph Prager; Tessa Lafontaisie; Michele Lafontaisie; Al Sunshine of television station CBS 4 South Florida; Gloria Tilley; Colleen Murphy; and Sherrie Maykut). Some of the comments also mentioned cancers other than lung and bladder that may result from arsenic exposure, as well as possible health effects of exposure to chromium.

**Response:** CCA contains copper and chromium compounds in addition to arsenic, but the staff determined that arsenic is the most potent of these three chemicals. In other words, smaller doses of arsenic will cause adverse health effects, compared to copper and chromium. Staff acknowledges that arsenic causes both acute and chronic health effects. However, cancer is the most sensitive endpoint. Thus, the staff's risk assessment is focused on arsenic-induced cancers. Any acute or chronic health effects other than cancer would be in addition to those estimated for cancer. Additionally, there would be a lower risk of health effects from chromium than from arsenic but any such health effects, including cancer, would be in addition to the arsenic-induced health effects.
The staff does not expect that acute or chronic non-cancer arsenic toxicity will be a regular outcome of normal contact with CCA-treated wood play structures. The staff acknowledges the cases of adverse health effects reported by parents and other consumers, but we believe that the unusual characteristics of the wood (e.g., covered with white residue, and leaking colored liquid), or specific behaviors (e.g., ingestion of rainwater that collected on the surface of the structure) that were reportedly associated with adverse health effects in these specific cases are not typical of most CCA-treated wood products or of children and their playtime behaviors with CCA-treated wood play structures.

The staff also recognizes that arsenic exposure is associated with cancers other than lung and bladder cancer, including the characteristic skin cancers. The staff focused on the two internal cancers because of the relative potency of arsenic-induced bladder and lung cancer and the quality of the data used to evaluate the dose-response relationship. Any increased risk for skin or other cancers from arsenic exposure would be in addition to the calculated risk for lung or bladder cancer.

**Comment:** A number of commenters disputed the staff's conclusions based on the findings or statements by other organizations. Some commenters (Tom Wittik of Woods Run Forest Products; Michael Draper of Forest Products Industry; Wendy Gramm and Susan Dudley of the Mercatus Center; Sharon Kneiss of the American Forest and Paper Association; Angela Logomasini, on behalf of the Competitive Enterprise Institute; and Darrell McKigney of the Small Business Survival Committee) mentioned the findings of the Florida Physicians Arsenic Workgroup. In addition, two other commenters (Carol Dawson of Consumer Alert; and Jody Clarke of the Competitive Enterprise Institute) maintain that there is no evidence of adverse effects of CCA-treated wood.

Several commenters (Tom Wittik of Woods Run Forest Products; Michael Draper, on behalf of Forest Products Industry; Steven Lamm and Michael Kruse, on behalf of the Wood Preservation Science Council; Sharon Kneiss of the American Forest and Paper Association; and Darrell McKigney of the Small Business Survival Committee) referred to the EPA release in February 2002 or to Mr. Housenger's statements at the Commission's public hearing on March 17, 2003, in which EPA stated that they have not concluded that CCA-treated wood poses unreasonable risks to the public.

One commenter (Floyd Frost, on behalf of the Wood Preservation Science Council) provided some information on childhood exposure to arsenic, unrelated to CCA-treated wood.

**Response:** The staff does not believe that the lack of well-documented clinical reports of CCA-treated wood-related illness is proof that adverse outcomes are not possible.

It is not always possible to know with certainty whether a health outcome is caused by a specific exposure. Arsenic has some characteristic effects, both acute and chronic, but other effects have multiple causes, especially those caused by lower doses or that occur later in life such as cancer. Therefore, even if arsenic exposure from CCA-treated wood has caused an adverse health effect in a person, it is likely not possible to definitively identify the exact cause of the particular person's illness, since it is possible that its occurrence may be due to more than one factor.
The staff estimate of average exposure is below levels expected to cause obvious clinical effects in children (e.g., vomiting, heart rate changes, or neuropathy), although the staff recognizes that there are possible scenarios involving contact with CCA-treated wood by children that could result in high exposures and associated clinical health effects. The staff has determined that there is the potential for certain arsenic-associated adverse effects during one’s lifetime from contact with CCA-treated wood. However, theoretical risk estimates do not allow one to know which persons will be affected or when in their lives they will be affected.

While the staff believes that exposure to arsenic from CCA-treated wood may increase the risk of health effects, including cancer, such effects would be difficult to document. The staff is not aware of any epidemiological study examining the relationship between adverse health effects and contact with CCA-treated wood structures. The staff, however, has received reports of illness associated with exposure to CCA-treated wood structures (Tessa Lafantaisie; Michele Lafantaisie; Al Sunshine of television station CBS 4 South Florida; Gloria Tilley; Colleen Murphy; and Sherrie Maykut), and is aware of additional reports in the media. The staff acknowledges that the adverse effects in these reports have not necessarily been proven to be linked to the CCA-treated wood.

EPA’s conclusions

While it is correct that EPA has not concluded that CCA-treated wood poses unreasonable risks, the staff believes it is more accurate to state that EPA has not yet finished its assessment.

The staff understands that EPA is continuing to study this issue and is currently conducting cancer and non-cancer risk assessments relating to use of CCA-treated wood products. EPA’s analysis includes children’s contact with CCA-treated wood playground structures. EPA has not indicated what it expects the outcome of its assessments to be, but EPA staff has stated that “the completion of this investigation of potential risks to children from exposure to CCA-treated wood is a priority for the agency” (Housenger, 2003).

Florida Physicians Arsenic Workgroup

A discussion of the Florida Physicians Arsenic Workgroup report on CCA-treated wood is found in the staff’s response to Question 14, posed by Commissioner Moore.

Other assessments of CCA-treated wood

One comment mentioned two other risk assessments that concluded that contact with CCA-treated wood structures would not result in excess cancer risk (Wendy Gramm and Susan Dudley of the Mercatus Center).

The first study, attributed by the commenters to Dr. Christopher Teaf of Florida State University, was conducted by Hazardous Substance & Waste Management Research, Inc. (Hazardous Substance & Waste Management Research, Inc., 2001), under contract with representatives of the wood treatment industry. The commenters claimed that this study showed that a residue level of 420 μg arsenic per 100 cm² of wood would be safe for a child and that most wood has surface residue values that are much lower than this.
The staff notes that the 420 μg/100 cm² level is based on non-cancer effects. However, the staff believes that cancer is the most important endpoint for risk assessment. For cancer, this study calculated that the “safe” level would be substantially lower, about 40 μg/100 cm². The staff cannot directly compare these results with the results of the staff’s assessment, since these levels are wood surface residues, not levels on hands after contact with the wood, and because the assessment was based in part on exposures during adulthood. However, a close look at the authors’ methods shows that they assumed that only a small fraction of the arsenic available on the surface of the wood would be picked up onto hands and subsequently transferred to the mouth. In other words, the “safe” level for wood surface residues (40 μg/100 cm²) presented in this report corresponds to a much lower “handload” level (about 5 μg per handload) that is similar to what has been measured by CPSC staff (average 7.6 μg per handload) and others (Thomas, 2003).

The staff believes that the commenters incorrectly interpreted this study as showing that relatively high levels of arsenic residue on the wood surface would be safe. On the contrary, based on the amount of arsenic assumed by the authors to be picked up onto the hands, the staff believes that the results are, in fact, consistent with the staff’s results that indicate an excess risk at the levels of exposure children may experience, as measured by actual transfers of arsenic from the wood to the hands.

The other assessment mentioned by the commenters was conducted by Gradient Corporation (Gradient Corp., 2001), under contract with two producers of CCA wood treatments. The lower estimated risk that results from the Gradient analysis compared to the CPSC staff analysis is due to differences in the exposure assessment, in which Gradient assumed a lower exposure frequency and relative bioavailability, and to the use of a unit risk that is lower than the values used by the CPSC staff. The CPSC staff believes that our exposure assessment, including the values chosen for exposure frequency and bioavailability, is appropriate given the limited available data and represents reasonable and foreseeable handling and use. Further, the staff maintains that the dose-response analyses by the National Research Council and the EPA Office of Water were conducted using reasonable and appropriate methods, and that the resulting range of unit risk values is reasonable given the limitations of the data used to derive these values.

Dr. Frost presented results from an unpublished retrospective cohort study of more than 3,000 people who had lived near a copper smelter during childhood. He reported that this study found no relationship between exposure and cancer mortality. However, few details were provided on the study design, sample size, exposure assessment, or statistical analysis. Without reviewing the full protocols and the characteristics of the study populations, the staff cannot comment on the adequacy of the methodology to overcome the likely difficulties in studying arsenic-related cancers in the U.S. In addition, the staff believes that all relevant studies must be considered and that one negative study does not negate the studies that show an effect from the exposure.

Comment: Several commenters claimed that even if the staff’s risk estimates are valid, the risks are actually very small, especially in the context of all bladder and lung cancer cases from all causes (Carol Dawson, on behalf of Consumer Alert; Wendy Gramm and
Susan Dudley of the Mercatus Center; Jody Clarke of the Competitive Enterprise Institute).

Response: The CPSC staff estimated an increased lifetime risk of bladder or lung cancer of approximately two to 100 per million due to exposure to arsenic for a person who plays on CCA-treated wood playground structures during early childhood. This risk is in addition to the risk from all other causes of these cancers. The staff is concerned about arsenic in CCA-treated wood because this particular exposure can result in an increased risk of lung or bladder cancer.

The choice of an acceptable risk value is primarily a policy or societal decision, rather than a scientific one. As discussed in CPSC’s Chronic Hazard Guidelines (CPSC, 1992), a risk of one per million is the risk level that is generally considered by federal agencies as relevant for regulatory considerations of the risk from carcinogens. The one per million acceptable risk is a default value. The guidelines were intended, in part, to assist manufacturers in determining whether their products require labeling under the Federal Hazardous Substances Act (FHSA). In considering a possible regulatory action, the Commission generally considers the entire scope of possible alternatives, which, if action were initiated under the FHSA, might include labeling or a ban. The Commission may consider many factors, such as the nature and size of the exposed population and the balancing of costs related to the exposure with the benefits of the exposure. For these reasons, the Commission may decide on what is an acceptable risk on a case-by-case basis.

Comment: Several commenters, writing on behalf of the Wood Preservative Science Council (Jim Hale and Seth Goldberg, Gradient Corp., Joyce Tsuji, and Gary Williams) stressed that regulation of CCA-treated wood playground structures is not appropriate since, in their opinion, this source of exposure is so small compared to a lifetime’s worth of exposure to arsenic in food and drinking water.

Response: Please refer to the staff’s response to Question 7, posed by Commissioner Moore.

Comment: Several commenters discussed myriad issues relating to quantifying the carcinogenicity of arsenic, i.e., the dose-response relationship, or unit cancer risk (Carol Dawson from Consumer Alert; Wendy Gramm and Susan Dudley, on behalf of the Mercatus Center; Jim Hale and Seth Goldberg, Gradient Corp., Floyd Frost, Gary Williams, and Steven Lamm and Michael Kruse, on behalf of the Wood Preservative Science Council; David Crowe, of the National Association of Home Builders; and Kenneth Brown, and Angela Logomasini, on behalf of the Competitive Enterprise Institute). Some of the issues raised include the reliance on the analyses by the National Research Council Subcommittee on Arsenic in Drinking Water (NRC, 2001) and the EPA Office of Water (EPA, 2001); relevance of data from Taiwan and South America, studies conducted in U.S. populations, the implications of exposure to relatively low levels of arsenic, issues related to the science and statistics of the various epidemiological studies, and issues related to variability and uncertainty. Several commenters disagreed with the staff’s reliance on the analyses of NRC and EPA. Specific issues included the exposure assessment, dose-response modeling, low-dose extrapolation, and relevance to U.S. populations.
Response:  

Epidemiological Data

EPA and the National Research Council (NRC) relied on studies from a region of southwest Taiwan with high arsenic drinking water concentrations. Tseng and coworkers (Tseng et al., 1968; Tseng, 1977) studied a population in an area of southwest Taiwan that began using artesian wells containing up to 1,820 parts per billion (ppb) arsenic about 1910. In the 1960s, more than 40,000 residents were examined for hyperpigmentation, keratosis, and skin cancer. Chen and coworkers used death certificate data from villages in the same region to assess liver, lung, and bladder cancer mortality (Chen et al., 1985; Chen et al., 1986; Chen et al., 1988; Wu et al., 1989; Chen and Wang, 1990; and Chen et al., 1992).

These studies are ecological epidemiology studies in that exposures were not ascertained for individual subjects. Rather, exposure was assigned to individuals or to groups of individuals based on residence. A weakness of these studies is the ecological design. It is possible that well-water arsenic levels changed over time, or that residents moved or used different wells during their lives. Moreover, some villages had multiple wells with widely differing arsenic levels. Thus, there is likely uncertainty in the actual exposures experienced by each villager. Nonetheless, these studies have certain strengths (e.g., large size, and extensive population records) and are generally considered adequate for estimating the dose-response relationship between arsenic ingestion and development of cancer (Lee, 1990b; EPA, 1998; EPA 2001; NRC, 1999; NRC, 2001).

Further, several studies in other regions with very different populations and different study methodologies (e.g., Chile, Argentina, northeast Taiwan) support the association between arsenic ingestion and cancer (Hopenhayn-Rich et al., 1998; Ferreccio et al., 2000; Chiou et al., 2001) despite the expected differences in genetic susceptibility, nutrition and other lifestyle factors, and in the level of exposure to arsenic. While each of these epidemiological studies suffers from limitations and weaknesses, they lead to similar conclusions regarding the relationship between arsenic exposure and cancer.

U.S. studies

Some commenters argued that because of the likely differences between populations in the U.S. and other countries, such as Taiwan, risk assessment should be based only on studies conducted in the U.S.

Experts have debated this for many years. Critics charge that the largely rural populations in Taiwan and South America may have genetic or nutritional susceptibilities to cancer that are not found in the U.S., and that the arsenic exposures in these countries are so high compared to the U.S. that they cannot be used to develop dose-response models appropriate for the lower U.S. exposures (Carlson-Lynch et al., 1994; Rudel et al., 1996; Stöhrer, 2001). On the other hand, EPA (2001), NRC (2001) and others (Smith et al., 1992; Steinmaus et al., 2000) argue that despite the weaknesses in the epidemiology studies and the uncertainties about extrapolating to the U.S. population, there is no evidence that the Taiwanese or South American
populations are particularly susceptible to the toxic or carcinogenic effects of arsenic compared to U.S. populations. Although the population of southwest Taiwan is rural and poor, and consumes a diet dependent largely on sweet potatoes and rice, other populations with increased cancer mortality associated with arsenic in drinking water (Chile, Argentina, and northeast Taiwan) have no discernible nutritional deficiencies compared to the U.S.

Several epidemiological studies in the U.S. have not detected increased cancer incidence in populations with elevated arsenic drinking water levels (up to about 200 ppb) (Morton et al., 1976; Lewis et al., 1999). However, these studies of relatively small populations did not have sufficient statistical power (i.e., the statistical ability to draw conclusions about differences or changes in disease rates) to detect the small increases in cancer incidence that would be expected at the relatively low doses experienced by the U.S. populations.

In addition, the study by Lewis et al. (1999) of a Utah cohort shows that the exposed cohort had a significantly lower incidence of cancers compared to the statewide Utah population, which suggests that the cohort differed from the larger population in important ways. For example, the cohort was rural and belonged to a religion with strict lifestyle rules, while the larger Utah population includes several urban centers and represents a variety of religious and cultural backgrounds.

EPA (2001) and NRC (2001) have both concluded that an increased incidence of cancer due to the generally low arsenic exposures in the U.S. would be difficult to detect over the relatively high background rates of cancer in this country. Dr. Frost maintains that it would be feasible to detect excess cancers due to arsenic in the U.S., and refers to a published correspondence on the statistical ability to detect arsenic-related cancers (Frost et al., 2002). In this letter, the authors discuss some of the difficulties epidemiologists face in studying this issue in the U.S., and they state, "(w)e would agree that a study of current lung cancer risks in the general population could be problematic for water arsenic exposures ≤ 0.050 mg/L."

There are populations in the U.S. that consume water containing greater concentrations of arsenic than this, but even so, Frost et al. (2002) mention several potential problems that investigators and study designs will have to overcome in order to detect the effects (e.g., the effects of smoking, latency [the length of time between exposure and appearance of the disease], and migration [movement of people into and out of the study area]). It's not clear that the methodology of any current or proposed study is adequate to overcome the potential problems in detecting arsenic-related cancers in the U.S.

The few published studies of U.S. populations likely did not have sufficient sample size to detect a relationship between arsenic exposure and cancer. Although the staff believes the published analysis of Lewis et al. (1999) was flawed because of the likely differences between the exposed and referent populations, EPA has subsequently reanalyzed the data without the use of a referent population (EPA, 2000b). The reanalysis showed that, statistically, this study could not show whether exposure to arsenic in the population caused cancer. Thus, EPA concluded that the Utah study did not have enough statistical power for use in risk assessment.
In addition, during discussion with the Commissioners at the March 17-18, 2003 public hearing, both Dr. Beck and Dr. Tsuji (on behalf of the Wood Preservative Science Council) stated that it would be difficult to detect arsenic-related cancers in U.S. populations.

*Dose-response modeling and extrapolation*

There are two important issues in the dose-response modeling and quantitative risk assessment by EPA and NRC, 1) modeling the dose-response data from the studies of the exposed populations, and 2) extrapolating from that data to the lower doses expected in the population of interest. In general, in conducting these analyses, the biostatisticians choose a point on the dose-response model within the range of observed exposures, such as the dose that is associated with a 1% increase in the excess risk of cancer (called the 1% effective dose or ED01), and extrapolate linearly from that point to zero. The slope of this line is used to calculate the cancer unit risk. In contrast, the dose-response model that is fitted to the observed data may or may not be linear, depending on the data. The extrapolation in the low-dose region (lower than observed exposures in the study population) usually takes the linear form because the true shape of the relationship is unknown.

Dr. Frost expressed concern about linear curve fitting without clearly addressing the two separate parts of the analyses. EPA and NRC chose to use two different mathematical models to describe the dose-response data from the epidemiology studies of southwest Taiwan, and both chose linear extrapolation from the ED01 of their respective dose-response curves. While neither of the models used by EPA or NRC to describe the southwest Taiwan data are linear as presented graphically, both analyses include dose in the mathematical model as a linear term. In other words, cancer is directly proportional to arsenic dose. Analyses by others support this approach. For example, Byrd et al. (1996) analyzed the data from southwest Taiwan and concluded that “in contrast to the findings for skin cancer, the internal cancer cases exhibit a directly proportional relationship with arsenic dose rate, except for female kidney cancers, and even these have less curvature than the female skin cancer cases.” In addition, Brown et al. (2003) chose a linear relative risk model for the data from multiple studies in Taiwan, Chile, and Argentina.

Commenters (Hale and Goldberg, Frost, Lamm and Kruse; Brown) argued that the data show that highly exposed people have high rates of arsenic-related disease, including cancer, but that there is no evidence that low exposures, such as in the U.S., cause proportional rates of disease. Rather, these commenters argue that there is a threshold for exposure, below which cancer will not occur. As discussed above, it is possible that low levels of exposure cause cancer in some proportion of the population, but that increased incidence of cancer due to the generally low arsenic exposures in the U.S. would be difficult to detect over the relatively high rates of cancer from other causes.

Knowledge of a chemical’s mechanisms of action sometimes provides information about low-dose effects. However, arsenic is known to have widespread adverse effects on multiple cellular and organ systems; a number of these effects could be involved in

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6 Co-author Steven H. Lamm has submitted comments concerning Petition HP01-3 on behalf of the Wood Preservative Science Council (CH01-2-51).
carcinogenicity. Each effect has its own dose-response relationship, and any group of people has varying genetic, nutritional, lifestyle, and other characteristics so that we would expect that at the population level the overall dose-response relationship would be quite complex. Epidemiological studies are used to measure the final outcome (i.e., cases of cancer) of numerous distinct and interactive effects within a population of individuals with varying susceptibilities.

The EPA, in its two FR notices concerning the drinking water rules (proposed rule, EPA, 2000a; final rule, EPA, 2001), explicitly described and defended the use of linear extrapolation for low doses. EPA discussed the possible modes of action of arsenic and the evidence that suggests a non-linear dose-response effect. However, EPA stated that because no specific modes of action have been identified for arsenic carcinogenicity, they could not rule out linearity. "Therefore, in accordance with the 1986 cancer guidelines, and subsequent guidance discussed later, the Agency cannot reasonably use anything other than a linear mode of action to estimate the upper bound of risk associated with arsenic exposure." (EPA, 2001). For similar reasons, the NRC also used linear extrapolation.

Thus, while there are multiple hypothesized modes of action for arsenic, there is no one mode that is agreed upon by the scientific community, and a linear relationship cannot be ruled out. The CPSC staff agrees with the analyses of the available data conducted by EPA and the NRC. In addition, this approach is consistent with the Commission's Chronic Hazard Guidelines.

One comment from Steven Lamm and Michael Kruse (on behalf of the Wood Preservative Science Council,) also argued that using linear extrapolation results in a single unit risk value, and that therefore we must assume that the risk of cancer is constant over all doses (including very high doses) and different sources of exposure. However, the staff maintains that the quantitative analyses by EPA and NRC are based on standard risk assessment practices, and that risk assessors who conduct these types of analyses, including CPSC staff, recognize that the unit risk or cancer slope factor derived from low dose extrapolation is reserved for use in estimating risk in low-dose situations, and should not be applied to high-dose situations. The staff maintains that the unit risk values derived from the quantitative analyses of EPA and NRC are appropriate for use in estimating the risk from the ingestion of arsenic from contact with CCA-treated wood playground equipment.

While there are several other important issues related to the statistical handling of the data and extrapolation to the U.S. population, these issues have been discussed in detail by CPSC staff (Hatlelid, 2003a,b) and others (EPA 1998; EPA 2000a; EPA 2001; NRC 1999; NRC 2001). The staff recognizes that scientists, statisticians and risk assessors, while guided by standard practices and agency guidance (e.g., CPSC, 1992), come to conclusions about available data and make decisions in modeling and extrapolation based on expert judgment, experience, and individual interpretation of information, and thus the conclusions reached by different scientists may differ substantially.

The staff believes that despite the shortcomings of the available data and the different choices made by EPA and NRC experts, several reasonable approaches to quantifying
the risk of cancer from ingestion of arsenic exist. The CPSC staff believes that the quantitative assessments by NRC (2001) and EPA (2001) are both reasonable and appropriate. Therefore, the CPSC staff risk assessment was based on the range of unit cancer risk estimates from these two analyses.

Dr. Williams suggested that arsenic could have a hormetic effect (i.e., it could have a beneficial effect at low doses). Arsenic is a known human carcinogen. It has widespread adverse effects on multiple cellular and organ systems. A number of these effects could be involved in causing cancer. On the other hand, arsenic is known to induce apoptosis (an organized cell death) in certain cancer cells, but not in normal cells, and it has therapeutic value in the treatment of acute promyelocytic leukemia (see discussion in NRC, 2001). However, as discussed above, the final outcome of exposure to arsenic in any individual person is the result of numerous distinct and interactive effects within the body, most of which are harmful. As yet, the staff is not aware of any research that shows that at low doses, arsenic has an overall beneficial effect in human populations.

**CPSC staff calculation error**

Two comments (Jim Hale and Seth Goldberg, and Gradient Corp., on behalf of the Wood Preservative Science Council) claimed that the staff made an error in calculating the unit cancer risk from the quantitative analysis of the EPA. The staff disputes this claim.

Gradient provided an extensive discussion of the procedure for calculating the unit cancer risk from the information published in the Federal Register notice for the final rule for arsenic in drinking water (EPA, 2001). The Gradient analysis assumed that the risks presented in Tables III.D-2(a-c) for specific arsenic levels were the risks associated with exposure for a person of a specified body weight, lifetime, and drinking water intake. However, EPA presented population risks for U.S. lung or bladder cancer in this notice, not theoretical risks to individuals consuming water with specific arsenic concentrations. More precisely, the risks presented were the mean risks calculated for the U.S. exposed population after water treatment to a specified maximum arsenic concentration, taking into account current occurrence levels in drinking water in the U.S. Thus, the estimated risk is for the population that would be exposed to a range of arsenic levels up to the specified maximum level; only a fraction of the population would be consuming drinking water with the maximum allowable concentration. Further, EPA assumes in its calculations that treated water will actually contain no more than 80 percent of the specified maximum value based on their experience with water treatment systems. Therefore, the unit risks cannot be estimated directly from the information published in the notice.

Additional information provided by EPA staff allowed the CPSC staff to calculate the unit cancer risks used in EPA's analysis. EPA staff assumed two different levels of background arsenic exposure for the Taiwanese population, as well as two levels of drinking water intake, which results in "low" and "high" risk estimates. Thus, EPA's population risks were based on a unit risk range of about 0.00041 to 0.0037 (µg/kg/day)^1 for bladder or lung cancer for males and females combined, and
the CPSC staff stands by the accuracy of the unit risk estimate used in the staff's risk assessment (Hattelid, 2003b).

B. Economic Considerations

Comment: Several commenters offered economic justifications against a “ban” of chromated copper arsenate (CCA)-treated wood. Among the arguments were assertions that the alternatives to CCA were inferior or also posed environmental or health risks. It was also asserted that the alternative chemicals will cause some fasteners to corrode (Tim McMahon, consumer; Tom Wittek for Woods Run Forest Products, Inc; Carol Dawson for Consumer Alert; Wendy Gramm for the Mercatus Center at George Mason University), the cost of the wood will increase (Tim McMahon, consumer; Terrance Scanlon for Capital Research Center; Wendy Gramm for the Mercatus Center at George Mason University), and that CPSC action may cause other disruptions in the market for all forms of treated wood (Michael Draper for the Western Region of the United Brotherhood of Carpenters and Joiners of America). There were some comments that a ban on CCA would reduce the number of playgrounds, depriving some children, especially children from less affluent households, of the benefits of playing on playgrounds (Terrance Scanlon for Capital Research Center; Wendy Gramm for the Mercatus Center at George Mason University; Hal Storey for S.I. Storey Lumber; and Angela Logomasini for the Competitive Enterprise Institute). Some commenters suggested that the chemical companies that agreed to cancel the registrations of CCA may have been motivated as much by a desire to increase the sales of more profitable products that could not compete against CCA as they were by concerns for public safety (Tom Wittek for Woods Run Forest Products, Inc; Wendy Gramm for the Mercatus Center at George Mason University). One commenter alleged that one of the petitioners, the Healthy Building Network, might have been motivated by potential financial gain if the use of CCA for residential purposes was banned (Carol Dawson for Consumer Alert).

Response: The CCA registrants voluntarily requested that the Environmental Protection Agency (EPA) cancel most residential-use registrations. EPA granted these requests, effectively banning use of CCA for treating wood for most residential uses after December 31, 2003. Whatever action the Commission takes with regard to the petition, it will not impact that cancellation or the economic impact that results from that EPA action.

Comment: Sharon Kneiss for the American Forest and Paper Association asserted that if CPSC took action that suggested that CCA posed health risks, it could adversely impact the market for continuing industrial uses of CCA-treated wood and may even disrupt the market for non-arsenical wood preservatives.

Response: The comment is speculative. The cancellations finalized by EPA were at the request of the industry and will result in changes in the preservative-treated wood market irrespective of any CPSC action.
References


www.umasssoils.com/abstracts2003/Wednesday/ccapart1.htm


CONSUMER PRODUCT SAFETY COMMISSION

Petition HP 01–3 Requesting a Ban of Chromated Copper Arsenate (CCA)-Treated Wood in Playground Equipment

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of public meeting.

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) will conduct a public meeting on March 17, 2003 to receive comments on the CPSC staff briefing package on petition HP 01–3 requesting a ban of chromated copper arsenate (CCA)-treated wood in playground equipment. The CPSC staff will also brief the Commission on the package on that date.

The focus of the discussions will be the supporting information developed by CPSC staff that is described in the February 7, 2003 briefing package entitled Petition to Ban Chromated Copper Arsenate (CCA)-Treated Wood in Playground Equipment. The Commission invites oral presentations from individuals, associations, firms, and government agencies with information or comments related to the briefing package. The Commission will evaluate these presentations in its deliberations on petition HP 01–3.

DATES: The CPSC staff will brief the Commission on the issues at 10 a.m. on March 17, 2003. Oral presentations by commenters will begin at 2 p.m. on that date. In the event that time constraints require it, the meeting may continue to the next day. No oral presentations will be permitted by persons who do not submit briefs to testify and the text of the presentation by February 28, 2003. Requests to make oral presentations, and 10 copies of the text of the presentation, must be received by the CPSC Office of the Secretary no later than February 26, 2003. Persons making presentations at the meeting should provide an additional 50 copies for dissemination on the date of the meeting.

Presentation texts should identify the author’s affiliation with, or employment or sponsorship by, any entity with an interest in the petitioner’s request that the Commission ban use of CCA-treated wood in playground equipment. The Commission reserves the right to limit the number of persons who make presentations and the duration of their presentations. To prevent similar presentations, groups will be directed to designate a spokesperson.

Written submissions, in addition to, or instead of, an oral presentation may be sent to the address listed below and will be accepted until March 28, 2003.

ADDITIONAL INFORMATION: The meeting will be in room 420 of the East-West Towers Building, 4330 East-West Highway, Bethesda, MD. Requests to make oral presentations, and texts of oral presentations should be captioned ACCA Ban Petition, Petition HP 01–3, and mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or delivered to that office, room 502, 4330 East-West Highway, Bethesda, Maryland 20814. Requests and texts of oral presentations may also be submitted by facsimile to (301) 504–0127 or by e-mail to spsc-as@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: For information about the purpose or subject matter of this meeting contact Patricia M. Bittner, M.S., Project Manager, Directorate for Health Sciences, U.S. Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–7263; e-mail: pbittner@cpsc.gov. For information about the schedule for submission of requests to make oral presentations and submission of texts of oral presentations, contact Rockelle Hammond, Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–6853; fax (301) 504–0127; e-mail: rhammond@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

By a submission dated May 22, 2001, the Environmental Working Group (EWG) and the Healthy Building Network (HBN) requested that the Commission enact a ban on use of chromated copper arsenate (CCA)-treated wood in playground equipment. The submitters asserted that a ban is necessary because “[r]ecent research has shown that arsenic is more carcinogenic than previously recognized, that arsenic is present at significant concentrations on CCA-treated wood and in underlying soil, that the health risks posed by this wood are greater than previously recognized, and that past risk assessments were incomplete.” On June 20, 2001, that request was docketed as petition HP 01–3 under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261–1278.

The Commission solicited public comment on the petition by Federal Register notice of July 13, 2001. 66 FR 36756. Twenty-eight comments were received by the close of the comment period on September 11, 2001. The staff also held a public meeting on August 6, 2001 with members of the American Chemistry Council (representing CCA chemical manufacturers) and the American Wood Preservers Institute. On October 3, 2001, the staff conducted a public meeting with representatives of the petitioners. The comments from the
wood industry, environmental groups, trade associations, consumers, and state and local governments discussed toxicity issues, health risks from exposure to CCA-treated wood, CCA-treated wood as a possible hazardous substance under the FISMA, the levels of disobleagable arsenic present on the wood, the bioavailability of arsenic, exposure to arsenic in soil and groundcover, disposal issues, and whether the type of wood influences arsenic leaching.

The staff has completed its analysis of the petition and the comments received and has forwarded a briefing package to the Commission. The staff recommends that the Commission defer further action on the petition pending final action by the United States Environmental Protection Agency (EPA) on the request by the registrants of the CCA pesticide to cancel registrations for most, if not all, uses that involve treating wood for consumer uses, including for use in playground equipment.

B. The Public Meeting

The purpose of the public meeting is to provide a forum for oral presentations on the CPSC staff briefing package on petition HP 01–3 and the materials that are described in the staff briefing package.

Participation in the meeting is open. See the DATES section of this notice for information on making requests to give oral presentations at the meeting and on making written submissions.


Todd A. Stevenson,
Secretary, Consumer Product Safety Commission.

[FR Doc. 03–3824 Filed 2–13–03; 8:45 am]
BILLING CODE 6355–01–M

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Notice of Technical Assistance Conference Calls for Organizations Applying Directly to the Corporation for Funding Through the AmeriCorps*National Program Grant

AGENCY: Corporation for National and Community Service.

ACTION: Notice of technical assistance conference calls.

SUMMARY: The Corporation for National and Community Service (hereinafter the “Corporation”) will be providing a series of technical assistance conference calls for organizations applying directly to the Corporation for funding through the AmeriCorps*National Program. If you are applying for funding via a state commission, instead of applying directly to the Corporation, please contact your commission for assistance using the following link to choose your state and then find your state commission: http://www.national.service.org/about/family/commissions_pick.html.

Part A. AmeriCorps*National Guidelines and Application Instructions

We will hold a series of technical assistance calls to review the 2003–2004 AmeriCorps*National Application Instructions. Non-profit organizations intending to submit an application for an AmeriCorps*National program grant, to operate a program in two or more states, may participate in these calls. Participation in these calls is optional. The 2003–2004 AmeriCorps Guidelines and AmeriCorps*National Application Instructions are posted on our Web site at: http://www.americorps.org/resources/guidelines2003.html.

These calls will be recorded and available for replay. Call dates and times are as follows.

For organizations applying for NEW AmeriCorps*National program grants:
March 11, 2003, 1–2:30 p.m. EST.

For organizations applying for AmeriCorps*National PLANNING grants:
March 12, 2003, 1–2:30 p.m. EST.

For existing AmeriCorps*National Grantees applying for CONTINUATION grants:
March 26, 2003, 1–2:30 p.m. EST.

To Register for a Call: Select one of the call dates specified above, then contact Sueko Kumagai via e-mail (skumagai@cns.gov) or phone (202–606–5000, ext. #418) with your selected date. Please register no later than 3 days prior to your selected call.

Part B. AmeriCorps*National Application Toolkit Technical Assistance Calls

We will hold a series of technical assistance calls reviewing application toolkits. We have developed the toolkits with assist applicants with the performance measurement, tutoring, and faith-based and community initiative aspects of program design. Non-profit organizations intending to submit an application to the Corporation for an AmeriCorps*National program grant, to operate a program in two or more states, may participate in these calls. Participation in these calls is optional.

These calls will be recorded and available for replay. Call dates and times are as follows. Call-in information and replay information are provided for each call.

Performance Measurement Toolkit
Technical Assistance Conference Calls
Tuesday, February 18, 3 p.m. EST—for NEW AmeriCorps*National Applicants
PassCode: toolkit
Leader’s Name: Sueko Kumagai
Replay Number: (800) 835–8069. Replay available until: February 25, 2003, 3 p.m. EST

Tuesday, February 25, 4 p.m. EST—for current AmeriCorps*National Grantees
Leader’s Name: Sueko Kumagai.
PassCode: toolkit
Toll-Free Number: (888) 723–9816
Replay Number: (800) 294–9506. Replay available until: March 4, 2003, 4 p.m. EST

Faith Based and Community Initiatives Toolkit Technical Assistance Conference Calls
Wednesday, February 19, 2003, 3 p.m. EST—for NEW AmeriCorps*National Applicants
Leader’s Name: Sueko Kumagai.
PassCode: toolkit
Toll-Free Number: (888) 723–9816
Replay Number: (800) 489–7535. Replay available until: February 26, 2003, 3 p.m. EST

Wednesday, February 26, 2003, 4 p.m. EST—for current AmeriCorps*National Grantees
Leader’s Name: Sueko Kumagai.
PassCode: toolkit
Toll-Free Number: (888) 723–9816
Replay Number: (800) 839–9137. Replay available until: March 5, 2003, at 4 p.m. EST

Tutoring Toolkit Technical Assistance Conference Calls
Friday, February 21, 2003, 3:30 p.m. EST—for NEW AmeriCorps*National Applicants
Leader’s Name: Sueko Kumagai.
PassCode: toolkit
Toll-Free Number: (888) 723–9816
Replay Number: (800) 925–2387. Replay available until: February 28, 2003, 3 p.m. EST

Friday, February 28, 3 p.m. EST—for current AmeriCorps*National Grantees
Leader’s Name: Sueko Kumagai.
PassCode: toolkit
Toll-Free Number: (888) 723–9816
Replay Number: (888) 568–0350. Replay available until: March 7, 2003, at 3 p.m. EST

We will schedule additional technical assistance calls for the toolkits for
APPENDIX B
MEMORANDUM

DATE: March 31, 2003

TO
Patricia Bittner, HS

Through:
Todd A. Stevenson, Secretary, OS

FROM
Martha A. Kosh, OS

SUBJECT:
Petition HP 01-3: Petition for Ban on Use of CCA Treated Wood in Playground Equipment

ATTACHED ARE COMMENTS ON THE CH01-4a

Cont’d (CH01-4)

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<td>Betsy Ehrlich</td>
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<td>Stephen Rodia</td>
<td>7220 Prestwick Lane Portage, MI 49024</td>
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<td>Connie Brunelle</td>
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<td>Kristine Townsend</td>
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<td>2/25/03</td>
<td>Peter Vogt</td>
<td><a href="mailto:petervogt@videa-tv.com">petervogt@videa-tv.com</a></td>
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<td>CH01-2-36</td>
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<td>Tim McMahon</td>
<td>St. Paul, MN <a href="mailto:Timmc@attbi.com">Timmc@attbi.com</a></td>
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<td>CH01-2-37</td>
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<td>Tom Wittek Vice President</td>
<td>Woods Run Forest Products, Inc. 310 West Third Ave. Colfax, WI 54730</td>
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<td>CH01-2-38</td>
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<td>Theodora Sweeney</td>
<td><a href="mailto:Briggswe@aol.com">Briggswe@aol.com</a></td>
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<td>CH01-2-39</td>
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<td>Enid Narver</td>
<td>P.O. Box 203 Elsah, IL 62028</td>
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Petition HP 01-3: Petition for Ban on Use of CCA Treated Wood in Playground Equipment

CH01-2-40  3/17/03  Jeff Moreau  
CEO  
Northstar Vinyl  
moreau@northvinyl.com

CH01-2-41  3/17/03  Carol Dawson  
Consumer Alert  
1001 Conn. Ave, NW  
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CH01-2-42  3/17/03  Joseph Prager  
Publisher  
mail@bancca.org

CH01-2-43  3/17/03  T. Lafontaisie  
samgdil@attcanada.ca

CH01-2-44  3/17/03  M. Lafontaisie  
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CH01-2-45  3/19/03  Don Eaise Sr.  
DEaiseLmbr@aol.com

CH01-2-46  3/14/03  Al Sunshine  
Video in OS  
CBS 4 South Florida  
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Miami, FL 33172

CH01-2-47  3/27/03  Michael Draper  
Forest Products  
LMC Chairman &  
Industry, National  
Vice Chairman  
Management Committee  
Western Region  
P.O. Box 65175  
United Brotherhood  
Washington, DC 20035  
Of Carpenters and  
Joiners of America

CH01-2-48  3/28/03  Terrance Scanlon  
Capital Research  
Center  
1513 16th St, NW  
Washington, DC 20036

CH01-2-49  3/28/03  Jan Schakowsky  
Congress of the U.S.  
Member of Congress  
House of  
Representatives  
Washington, DC 20515

CH01-2-50  3/28/03  Wendy Gramm  
Mercatus Center  
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George Mason Univ.  
Regulatory Studies  
3301 N Fairfax Dr.  
Program &  
Suite 450  
Arlington, VA 2201  
Regulatory Studies  
Program
Petition HP 01-3: Petition for Ban on Use of CCA Treated Wood in Playground Equipment

CH01-2-51 3/28/03 Seth Goldberg Atty
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Washington, DC 20036

Barbara D. Beck
PhD, Toxicologist
Gradient Corp.

On behalf of the Wood
Wood Preservative
Science Council (WPSC)
P.O. Box 293
Mt. Vernon, VA 22121

Floyd Frost, PhD
Epidemiologist, Lovelace
Respiratory Research
Institute;

Joyce S. Tsuji, PhD
DABT, Exponent;

Gary M. Williams
Address same as above
Director of
Pathology and Toxicology
New York Medical College;

Steven H. Lamm
Address same as above
President,
Consultants in
Epidemiology

CH01-2-52 3/28/03 Sharon Kneiss
Vice President
American Forest and
Paper Association
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Washington, DC 20036

S.I. Story Lumber
Company, Inc.

CH01-2-53 3/28/03 Hal Storey

Debbie Burns
Vice President
Public Affairs
Southeastern Lumber
Manufacturers Assoc.

CH01-2-54 3/28/03 Kenneth Brown
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Chapel Hill, NC 27516

CH01-2-55 3/28/03 David Crowe
Sr. Staff
Vice President
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of Home Builders
1201 15th St, NW
Washington, DC 20005

CH01-2-56 3/28/03 Gloria Tilley
5783 Dover Road
Lakeview, NY 14085

CH01-2-57 3/28/03
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<td>Angela Logomasini</td>
<td>Competitive Enterprise Institute</td>
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<td>Director of Risk &amp;</td>
<td>1001 Connecticut Ave, NW, Suite 1250</td>
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<td>Environmental Policy</td>
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<td>Darrell McKigney</td>
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<td>1920 L St, NW</td>
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Memorandum

TO: Patricia M. Bittner, M.S., Project Manager, Directorate for Health Sciences

THROUGH: Hugh McLaurin, Associate Executive Director
Directorate for Engineering Sciences
Mark Kumagai, Acting Division Director
Division of Mechanical Engineering

FROM: Troy W. Whitfield, Mechanical Engineer
Directorate for Engineering Sciences

SUBJECT: Petition HP 01-03 - Petition for Ban on Use of CCA Treated Wood in Playground Equipment – EPA Federal Register Notice

Background

In June 2001, the U.S. Consumer Product Safety Commission (CPSC) docketed Petition HP 01-03, which asked the Commission to ban the use of chromated copper arsenate (CCA) treated (pressure-treated wood) in playground equipment. Chromated copper arsenate is a pesticide commonly used to treat dimensional lumber (pressure-treated wood) to protect the wood from deterioration and insect infestation. The petitioners assert that arsenic is more carcinogenic than previously known, arsenic is present in significant concentrations on CCA-treated wood and in underlying soil, the health risks posed by this wood are greater than previously recognized, and past risk assessments were incomplete. The Commission docketed the request for a ban as a petition under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261-1278. The petitioners’ request that the Commission review the safety of CCA-treated wood for general use was not docketed as part of the petition since no rulemaking would be involved.

In the February 22, 2002 Federal Register (Vol. 67, No. 36), the Environmental Protection Agency (EPA) announced receipt of requests from registered users of wood preservatives containing CCA to cancel certain CCA products and amend to terminate certain uses of other CCA products. In effect, certain pesticide treatments containing CCA will be cancelled, no longer manufactured or available, and others will be amended for use only under certain processes. Upon acceptance of the request, the sale, distribution, or use of the affected products will only be permitted if the sale, distribution, or use is within the terms described in the Federal Register notice (docket control number OPP-66300).
The following product registrations have been cancelled (Table 1.):

**TABLE 1. Cancelled Products**

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<tr>
<td>62190-5</td>
<td>WolmanacR Concentrate 70%</td>
</tr>
<tr>
<td>62190-11</td>
<td>CCA Type C 50% Chromated Copper Arsenate</td>
</tr>
</tbody>
</table>

The following manufacturing product registrations have been amended to reflect the cancelled uses (Table 2.):

**TABLE 2. Amended Manufacturing Products**

<table>
<thead>
<tr>
<th>EPA Registration Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>3008-66</td>
<td>Arsenic Acid 75%</td>
</tr>
<tr>
<td>10465-32</td>
<td>CSI Arsenic Acid 75%</td>
</tr>
<tr>
<td>62190-7</td>
<td>Arsenic Acid 75%</td>
</tr>
</tbody>
</table>

The following end use product registrations have been amended to reflect changes in the manufacturing product registrations (Table 3.):

**TABLE 3. Amended End Use Products**

<table>
<thead>
<tr>
<th>EPA Registration Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>3008-17</td>
<td>K-33-C (72%) Wood Preservative</td>
</tr>
<tr>
<td>3008-21</td>
<td>Special K-33 Preservative</td>
</tr>
<tr>
<td>3008-34</td>
<td>K-33 (60%) Wood Preservative</td>
</tr>
<tr>
<td>3008-35</td>
<td>K-33 (40%) Type-B Wood Preservative</td>
</tr>
<tr>
<td>3008-36</td>
<td>K-33-C (50%) Wood Preservative</td>
</tr>
<tr>
<td>3008-42</td>
<td>K-33-A (50%) Wood Preservative</td>
</tr>
<tr>
<td>3008-72</td>
<td>Osmose Arsenic Acid 75%</td>
</tr>
<tr>
<td>10465-26</td>
<td>CCA Type-C Wood Preservative 50%</td>
</tr>
<tr>
<td>10465-28</td>
<td>CCA Type-C Wood Preservative 60%</td>
</tr>
<tr>
<td>10465-32</td>
<td>CSI Arsenic Acid 75%</td>
</tr>
<tr>
<td>35896-2</td>
<td>Wood-Last Conc. Wood Preservative AQ 50% Solution CCA-Type A</td>
</tr>
<tr>
<td>62190-2</td>
<td>Wolmanac Concentrate 50%</td>
</tr>
<tr>
<td>62190-8</td>
<td>Wolmanac Concentrate 72%</td>
</tr>
<tr>
<td>62190-14</td>
<td>Wolmanac Concentrate 60%</td>
</tr>
</tbody>
</table>

The changes in manufacturing and end use product registrations also include labeling changes. The labeling changes include the acceptable preservative treatments of forest products according to American Wood-Preservers Association (AWPA) standards. A list of the acceptable uses (AWPA C-standards) for CCA to be effective December 31, 2003 according to the EPA Federal Register Notice is found in Table 4. Forest products treated with CCA may only be sold or distributed for the use described by the C-standard under which they were treated. The application of the C2 standard has been qualified for use on lumber and timber intended for saltwater use only. While not listed on the label, the C1 standard, All Timber Products, Pressure Treatment, is presumed to still be valid since it is considered the master standard and incorporated by modification into all the other standards.
TABLE 4. Acceptable Applications for CCA Pressure Treatment

<table>
<thead>
<tr>
<th>AWPA Standard</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2 (saltwater use only)</td>
<td>Lumber, Timbers, Bridges Ties and Mine Ties</td>
</tr>
<tr>
<td>C3</td>
<td>Piles</td>
</tr>
<tr>
<td>C4</td>
<td>Poles</td>
</tr>
<tr>
<td>C9</td>
<td>Plywood</td>
</tr>
<tr>
<td>C14</td>
<td>Wood for Highway Construction</td>
</tr>
<tr>
<td>C16</td>
<td>Wood Used on Farms</td>
</tr>
<tr>
<td>C18</td>
<td>Material in Marine Construction</td>
</tr>
<tr>
<td>C22</td>
<td>Lumber and Plywood for Permanent Wood Foundations</td>
</tr>
<tr>
<td>C23</td>
<td>Pole Building Construction</td>
</tr>
<tr>
<td>C24</td>
<td>Sawn Timber Piles Used for Residential and Commercial Building</td>
</tr>
<tr>
<td>C25</td>
<td>Crossarms</td>
</tr>
<tr>
<td>C28</td>
<td>Structural Glued Laminted Members and Laminations Before Gluing</td>
</tr>
<tr>
<td>C33</td>
<td>Preservative Treatment of Structural Composite Lumber</td>
</tr>
<tr>
<td>C34</td>
<td>Shakes and Shingles</td>
</tr>
</tbody>
</table>

Discussion

In an April 9, 2003 Federal Register Notice (Vol. 68, No. 68 pg. 17366), the EPA provided a formal response to the requests by registrants of pesticides containing chromated copper arsenate for cancellation of certain products and the termination of certain uses of other CCA products. The notice announces the EPA’s acceptance of certain requests for cancellation and termination of use, addresses the public comments received on the voluntary cancellation request, and defers a response on other portions of the request until more information is obtained.

The EPA acceptance of the voluntary cancellation/use terminations included labeling changes for acceptable applications of CCA products under the AWPA standards. One of the AWPA standards removed from the label includes, C17, “Playground Equipment Treated with Inorganic Preservatives, by Pressure Process”. The acceptance of the labeling change request addresses the concerns of the petitioner. Additionally, the labeling changes address a majority of the lumber processed for residential uses, another consideration by the petitioner. While use of CCA is still authorized for most industrial and commercial applications, usually with retention levels of 0.50 pounds per cubic foot (pcf) or more, dimensional lumber for residential use, typically treated under the C2 standard (0.40 pcf) (now reserved for salt water uses only) will now need to be treated with a different preservative.

The EPA has deferred decision on certain agricultural uses under the C9 and C16 standards. Plywood used on farms, as well as for roof decking, sub-flooring, flooring whether above ground or on ground contact are included in the C9 standard. Posts (including fences), poles, and piles with agricultural uses such as structural members on farms are covered by the C16 standard. The EPA will evaluate the uses of CCA under the remaining acceptable standards (risk, exposure and benefits assessment) and determination on the cancellation/termination of other uses will be made during the re-registration of the chemical. The EPA believes, through available information and field investigations, that the distribution channels, sizes, shapes, and
aesthetics make the agricultural fence posts specific to the farm use market and therefore not available on the residential market. Normally, fence posts for residential uses would have been processed under the C5 standard — no longer a valid use of CCA under the new labeling scheme.

Summary

The EPA has accepted most of the voluntary cancellation/use termination requests by registrants of wood preservative pesticide products containing chromated copper arsenate (CCA). The cancellation/use terminations which have been accepted address the petitioners’ specific concerns with regards to playground equipment (removal of the C17 standard process) as well as the processing of dimensional lumber for residential applications (limiting the C2 process to salt water use only). The EPA has deferred judgment on certain agricultural uses of CCA (fence posts and wood foundation applications) while they review the exposure, risk and benefit of all uses of CCA through the re-registration process. Because distribution channels, aesthetics, size, round shape, and random diameters of the fence posts treated under the C16 standard seem to limit their use to farm applications, and EPA has found that these posts are not sold on the residential market, EPA believes deferral is appropriate until further information is made available. At any time during the re-registration process, if information becomes available, the EPA will take the appropriate action – accept or refuse the cancellation/use termination request.

References

American Wood-Preservers’ Association Standards – 2001

Environmental Protection Agency Federal Register/Vol. 67, No. 36/ Friday, February 22, 2002/ Notices OPP-66300; FRL-6826-8