September 11, 2001

Todd A. Stevenson,
Acting Secretary
Office of the Secretary
Consumer Product Safety Commission
Room 501
4330 East-West Highway
Bethesda, MD 20814

Re: Petition HP01-3, Petition for Ban on the Use of CCA Treated Wood in Playground Equipment

Dear Mr. Stevenson:

The American Chemistry Council Biocides Panel Arsenical Wood Preservatives Task Force and the American Wood Preservers Institute (the Commenting Trade Associations) submit these Comments to the Consumer Product Safety Commission regarding the above-referenced Petition. The Commenting Trade Associations appreciate the opportunity to comment on the Petition. If you have any questions regarding these comments, please contact Hasmukh Shah, Manager of the Biocides Panel at 703-741-5637.

Yours truly,

American Chemistry Council
American Wood Preservers Institute

Cc: Frank T. Sanders,
Director, Antimicrobial Division
OPP, USEPA
John D. Graham,
Administrator of OIRA, OMB

Enclosure

Comments of the American Chemistry Council Biocides Panel Arsenical Wood Preservatives Task Force and the American Wood Preservers Institute To the Consumer Products Safety Commission in Response To a Petition for Ban on the Use of CCA-Treated Wood in Playground Equipment

Petition HP 01-3

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EXECUTIVE SUMMARY

The Arsenical Wood Preservatives Task Force of the American Chemistry Council Biocides Panel ("Task Force") and the American Wood Preservers Institute ("AWPI") (collectively, "the Commenting Trade Associations") submit the following comments on Petition HP 01-3, Petition for Ban on Use of CCA-Treated Wood in Playground Equipment.

The Commenting Trade Associations urge the Consumer Products Safety Commission ("CPSC") to recognize that the Environmental Protection Agency ("EPA") has exclusive jurisdiction over CCA-treated wood and its end uses. EPA regulates treated wood as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and is currently conducting a "comprehensive review [that] includes evaluating the potential risks to children on play-structures made of CCA-treated wood." Under the Federal Hazardous Substances Act ("FHSA"), CPSC does not have jurisdiction over pesticides regulated under FIFRA. In addition, parallel EPA and CPSC proceedings create the potential for duplicative and inconsistent regulation. To avoid this possibility, the Commenting Trade Associations urge CPSC to recognize that EPA, not CPSC, has jurisdiction to regulate CCA-treated wood.

In addition, even if CPSC believes it can exercise jurisdiction, in light of EPA's extensive regulation in this area, the Commenting Trade Associations believe it would at best duplicative and at worst risk inconsistent regulation for CPSC to conduct any regulatory proceedings on uses of CCA-treated wood. EPA has extensive experience regulating treated wood and already has collected significant amounts of data on treated wood. Moreover, EPA has implemented both mandatory and voluntary restrictions on treatment standards, handling, labeling, marketing, and end uses of CCA-treated wood. Additional regulation by the CPSC is unnecessary, as EPA adequately regulates CCA-treated wood.

Finally, the Commenting Trade Associations have developed and continue to develop a substantial amount of data for risk assessment and risk management related to CCA-treated wood. This information demonstrates that treated wood playground equipment does not pose an unreasonable risk of harm to children or other consumers. There is no need for further regulatory action on the use of CCA-treated wood in playground equipment.

I. Introduction

The Arsenical Wood Preservatives Task Force of the American Chemistry Council Biocides Panel (the "Task Force") and the American Wood Preservatives Institute ("AWPI") (collectively, "the Commenting Trade Associations") appreciate the opportunity to comment on Petition HP 01-3, Petition for Ban on Use of CCA-Treated Wood in Playground Equipment ("petition").

The Task Force represents companies that hold registrations with EPA for arsenical wood preservatives such as chromated copper arsenate ("CCA") and companies that supply the registered active ingredients used in those formulations. The AWPI is the national industry trade association representing the pressure-treated wood industry throughout the United States. Member companies include wood pressure treaters, preservative manufacturers, and supporting companies.

Chromated copper arsenate ("CCA") is a waterborne wood preservative containing chromium, copper, and arsenic compounds that protects wood against decay from fungi and other pests. CCA is used for outdoor decks, fencing, and landscaping and highway applications, among other uses. The process used for treating wood is subject to strict industry and environmental standards. CCA-treated wood is an environmentally and economically sound solution to many construction needs.

The Commenting Trade Associations submit these comments to provide background information on the industry and treating process, and to make CPSC, as well as EPA and OMB, aware of several serious concerns with actions that the Commission might take in response to the petition:

1) EPA regulates treated wood as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and currently is conducting exposure and risk evaluations to determine whether restrictions relating to the use of CCA-treated wood in playground equipment are necessary. Under the plain language of section 1261(f)(2) of the Federal Hazardous Substances Act ("FHSA") and section 2052(a) of the Consumer Products Safety Act, CPSC does not have jurisdiction over pesticides regulated under FIFRA. Thus, CPSC does not have jurisdiction over CCA-treated wood, including its use in playground equipment.

2) EPA's historic and current actions demonstrate that it is actively engaged in the regulation of CCA-treated wood and its end uses. Over the last 25 years, EPA has collected a significant amount of data and developed substantial expertise on CCA, CCA-treated wood, and its end uses. EPA also has implemented both mandatory and voluntary restrictions on the treatment standards, handling, labeling, marketing, and permissible end uses of CCA-treated wood. In light of EPA's extensive regulation in this area, it would be both unnecessary and inefficient for CPSC to conduct its own regulatory proceedings on uses of CCA-treated wood. Parallel EPA and CPSC proceedings will create the potential for duplicative and inconsistent regulation.

3) The Task Force and AWPI have developed and continue to develop information for risk assessment and risk management related to CCA-treated wood. This information demonstrates that treated wood playground equipment does not pose an unreasonable risk of harm to children or other consumers. There is no need for further regulatory action on the use of CCA-treated wood in playground equipment.

II. Industry Overview

A. CCA Preservative and Its Uses

Chromated copper arsenate (CCA) is a pesticide formulation consisting of ions of three metals (arsenic, chromium and copper) in an aqueous solution. CCA also may be referred to as an inorganic arsenical. CCA protects wood from dry rot, fungi, molds, termites, and other pests that can threaten the integrity of wood products. Studies have shown that wood treated with CCA lasts ten to twenty times longer than untreated wood. See USDA Forest Service Forest Products Laboratory, "Comparison of Wood Preservatives in Stake Tests, 1995 Progress Report" (1995) (Attachment 1).

Inorganic arsenical wood preservatives are most commonly applied to wood intended for use in outdoor settings, such as decks, walkways, fences, gazebos, boat docks, playground equipment, highway noise barriers, sign posts, utility posts, and retaining walls. There are few up-to-date authoritative published sources of detailed statistical information about the industry and its products. Industry reports indicate that 144,506,900 pounds of CCA were used in 1996. See American Wood Preservers Institute, "1996 Wood Preserving Industry Production Statistical Report" (1996). Other waterborne preservatives amounted to 4,363,600 pounds. Id.

The estimated markets for the approximately seven billion board feet a year of CCA-treated wood currently produced can be broken into the following categories: Outdoor decks, 32 percent; Marine, 16 percent; Landscape, 12 percent (includes < 1% playground equipment); Highway, 9 percent; Fencing, 8 percent; Framing, 6 percent (to safeguard against termite destruction, most notably in Hawaii and Louisiana); Utility poles, 5 percent; Export, 2 percent; Pilings, 1 percent; Permanent wood foundations, 1 percent; and, Other, 8 percent (may include bed liners for utility trailers, cooling towers and shoring for excavations).

In the market for play equipment, preserved wood always has competed with metals and with woods such as cedar and redwood, which claim to be naturally decay-resistant. In addition, in recent years plastics have grown in popularity. The industry's best estimate is that the current demand for CCA-treated wood in play equipment is approximately 50 million board feet a year.

B. Process Description

1. Retort Process

In the basic treating process, the untreated (or "white") wood product is loaded onto small rail or tramcars. Using a vehicle such as a forklift, the trams are pushed into a large horizontal-treating cylinder. The cylinder door is sealed, and a vacuum is applied to remove most of the air from the cylinder and wood cells. Preservative solution (CCA) is then drawn into the cylinder and once the cylinder is filled, pressure is applied (often to about 150 pound per square inch) forcing CCA into the wood. See, e.g., Osmose, Inc., "Plant Operations" (1995).

Following this treatment cycle, pressure is released and the unabsorbed solution is returned to the storage tank for later re-use. A vacuum is drawn to remove excess solution from the wood to control drippage following treatment. At the end of the process, the cylinder door is opened and the trams are pulled out onto a drip pad, which is regulated by EPA under the Resource Conservation and Recovery Act (RCRA). See 40 C.F.R. Part 265, Subpart W. After the material on the drip pad has become surface dry, it can be removed from the drip pad. A Process Block Flow Diagram of a Waterborne CCA Wood Preserving Plant is Attachment 2.

2. Fixation Process

Fixation is the name of the chemical process in which the preservative metals in solution react with wood fiber molecules. Fixation is actually a series of chemical binding reactions between the water-soluble preservative metals and wood which results in an insoluble reaction product of the wood components and the preservative metals. Fixation reaction rates are affected by many factors, including temperature, concentration of reactants, and pH. Because the reaction series terminates with a precipitation reaction, the process is non-reversible. See Forest Products Society, "Selection and Use of Preservative-Treated Wood" (1995).

3. Retention Levels

CCA-treated wood may have a "retention" level ranging from 0.25 to 2.5 pounds per cubic foot ("pcf"). These numbers represent the amount of wood preservative on an oxide basis, i.e. CuO, CrO_3 and As_2O_5 in a cubic foot of wood. For example, a retention of 0.25 lb/ft^3 indicates that a minimum of ¼ pound of preservative is in every cubic foot of wood fiber in the "assay zone," defined by the American Wood Preservers Association for quality control purposes. A retention of 0.25 is considered adequate protection for lumber that is not in contact with the ground or in high moisture conditions. All lumber treated to 0.40 lb/ft^3 retention is suitable for ground contact, high moisture conditions, and freshwater contact. Other retentions are specified for various applications such as wood foundations, structural timbers, guardrails, etc. The retention levels for CCA-treated wood have been established by the American Wood-Preservers' Association. Playground equipment may be at a retention of 0.40 or a combination of 0.25 and 0.40.

C. AWPA Standards for Waterborne Preservatives

The American Wood-Preservers' Association (AWPA) is a non-profit technical society founded to provide a common forum for exchange of technical information between industry, research and users of treated wood. See American Wood Preservers' Association, "Introduction to the 1999 American Wood-Preservers Association Book of Standards" (1999). AWPA members include academic experts as well as industry representatives. AWPA is the principle standards-writing body for the wood preserving industry in the United States. AWPA standards help ensure that treated wood products perform satisfactorily for their intended use. They are recognized and used by most, if not all, specifiers of treated wood including electrical utility, marine, road and building construction, as well as by local, state and federal governments. Id.

Each year, AWPA produces a book of standards. The standards are divided into various sections. The Commodity Standards, or C Standards, contain treatment specification requirements for different commodities. Included are requirements for pretreatment conditioning needed for maximum preservative retention and penetration; for temperature and pressure to ensure maximum effective impregnation with minimal damage during the processing; and for such conditions as are necessary to obtain consumer acceptable products after treatment. Id. CCA-treated wood is approved by AWPA for a wide range of applications in a wide range of environments. The following C Standards are Attachments 3 and 4, respectively:

- C1-99, All Timber Products – Preservative Treatment By Pressure Process
- C17-98, Playground Equipment Treated With Inorganic Preservatives – Preservative Treatment by Pressure Process.

The Preservative Standards, or P Standards, contain specifications for all AWPA accepted wood preservatives and fire retardants. Standard P5-99 is the Standard for Waterborne Preservatives and is found in Attachment 5.

The M Standards are the Purchase Guide, Quality Control and Inspection Standards. The M Standards offer a guide for the purchaser of wood products on the quality control routines for wood preserving plants. Attachment 6 is the M3-99, Standard Quality Control Procedures For Wood Preserving Plants.

D. Quality Assurance

AWPA Standard M3-99 establishes quality control procedures for wood preserving plants. This standard requires the inspection of treated wood following treatment. This includes a visual inspection, and the boring of the treated material in each and every charge to determine conformance with the penetration specified. The wood borings are analyzed at the treating plant or by a third party. All treated material shall meet the minimum specified retention of the applicable AWPA Standard at the time of shipment from the plant. See AWPA, "AWPA Standard M3-99, Standard Quality Control Procedures for Wood Preserving Plants."

A strong quality control program is important in ensuring the production of a high quality product. When treated correctly, CCA-treated wood retains its structural integrity from ten to twenty times longer than untreated wood. See AWPI, "Answers to Often-Asked Questions about Treated Wood" (1995). The USDA Forest Products Laboratory has been researching the effectiveness of wood preservatives in stake tests since 1938. See USDA Forest Service Forest Products Laboratory, "Comparison of Wood Preservatives in Stake Tests, 1995 Progress Report" (1995) (Attachment 1). Attachment 7 is a summary of the condition of stakes in December of 1991 after about 24 years of service. Id. The data presented by the Forest Products Laboratory indicates the effectiveness of the CCA treatment to wood. If the wood were not retaining the CCA at the necessary levels, it would be evident in failures of stakes in test such as those set up by the Forest Products Laboratory.

E. Benefits

Wood, because of its abundance, has always been a common building material in North America. Moreover, trees are a renewable resource that can be harvested on a periodic basis much like any agricultural crop. With proper management, this resource can be both utilized and maintained. See Forest Products Society, "Selection and Use of Preservative-Treated Wood" (1995). For example, in 1991 the national net timber growth exceeded the volume harvested by a third, whereas in the 1920s the harvest was double the growth. See Powell, et al. "Forest resources of the United States, 1992" Gen. Tech. Rep. RM-GTR-234 (1992).

In addition to being renewable, wood is one of the most environmentally acceptable materials. From raw material extraction to finished product, the energy input is 70 times greater for a ton of aluminum than for a ton of lumber, and 17, 3.1, and 3 times greater for steel, brick, and concrete block, respectively, than for wood. See Forest Products Laboratory, "Wood Handbook: Wood as an Engineering Material" (1992).

Wood is also an excellent thermal insulator when compared to other construction materials. See Forest Products Society, "Selection and Use of Preservative-Treated Wood" (1995). For an equivalent thickness, solid wood is 4 times more efficient as an insulator than cinder block, 6 times more efficient than brick, 15 times more efficient than concrete, and 1,770 times more efficient than aluminum. See American Society of Heating, Refrigerating, and Air Conditioning Engineers, "Handbook, Fundamental I-P Addition" (1989). Finally, healthy, fast-growing forests managed by scientific silvicultural methods for long-term yield absorb carbon dioxide from the atmosphere and provide a net oxygen gain, thus reducing the greenhouse effect. See Forest Products Society, "Selection and Use of Preservative-Treated Wood" (1995).

Treated wood also has economic benefits compared to non-treated wood. The costs to replace untreated wood damaged by decay and insects runs into billions of dollars annually. Given labor costs, material costs, and the problems associated with the inconvenience of rehabilitation, it is difficult to imagine many long-term applications where the added cost of preservative treatment is not justified. Id.

F. Alternatives to CCA

CCA is the most widely used water borne wood preservative in the United States. Several alternative preservatives exist, although they are not approved for all applications such as marine applications. The principal alternatives to CCA include Alkaline Copper Quat ("ACQ") and Copper Azole. Non-wood alternatives would be steel, and, in some uses, plastic composites. Plastic composites can not be used for structural members.

G. Status of CCA Worldwide

The Center for Health Care's letter supporting the petition creates the impression that CCA is banned or restricted in many other countries. In fact, most countries still permit the use of CCA-treated wood, and in countries with use restrictions, there is no evidence presented that these restrictions were implemented in response to health or environmental concerns. In fact, the use of CCA-treated wood is most often limited by the market forces and demand in a particular country. For example, while CCA is not the preservative of choice in Japan, it is being used in areas with termite infestation problems, including the provinces of Okinawa and Kyushu. Sweden permits the use of CCA-treated wood in ground contact situations and where there is a safety risk or the timber is difficult to replace. CCA has been banned in The Netherlands and Indonesia.

Other countries have examined the use of CCA-treated wood in residential settings and expressly found that its use should be allowed. For example, CCA came under review in Australia in 1977. Concerns regarding the use of CCA-treated wood for playground equipment were satisfied with the widely distributed document called "Guidelines for Handling CCA Treated Timber." The document addressed the basic precautions to take when using CCA-treated wood. Three years ago Australian regulators once again reviewed the use of arsenic as a wood preservative. The Government was satisfied with the data presented to them and responded positively.

The European Union has enacted legislation that allows continued use of CCA pressure treatment preservatives and CCA-treated wood, although other uses of arsenical compounds are prohibited. See Directive 89/677/EEC.

III. CPSC Does Not Have Jurisdiction Over Pesticides Such as CCA-Treated Wood

In response to the Environmental Working Group and Healthy Buildings Network's petition for a ban on the use of CCA-treated wood in playground equipment, CPSC has indicated that it is proceeding under the Federal Hazardous Substances Act to examine the need for regulation.[1] See 66 Fed. Reg. 36756 (July 13, 2001). At the public meeting on August 6, 2001, CPSC staff asserted that CPSC had jurisdiction over the use of CCA-treated wood, commenting that EPA regulates the pesticide, but CPSC could regulate the wood. However, EPA regulates not only the liquid preservative, but also the treated wood itself as a pesticide under FIFRA, and has done so since 1988. Since CCA-treated wood is a pesticide under FIFRA, it is outside CPSC's jurisdiction.

The Federal Hazardous Substances Act, 15 U.S.C. §§ 1261 et seq. ("FHSA"), gives CPSC broad authority to set standards, require labeling, regulate, and even ban hazardous household substances. However, the FHSA excludes certain product categories from CPSC's jurisdiction, including pesticides. Through this provision, Congress expressed a clear intent that pesticides, as defined by FIFRA, would be regulated exclusively by EPA. Because EPA, the agency which implements FIFRA, has determined that CCA-treated wood is a pesticide subject to FIFRA regulation, treated wood is exclusively regulated by EPA and is outside CPSC's jurisdiction under FHSA.

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[1] The Petition also requested a review of other uses of CCA-treated wood. CPSC has not requested comments on restrictions on any other uses of CCA-treated wood; however, under the FHSA and CPSA, the CPSC does not have jurisdiction over these other uses of CCA-treated wood.

Under the FHSA, the CPSC has authority to declare certain articles "banned hazardous substances." 15 U.S.C. § 1261(q)(1). Before the CPSC may declare a substance "banned," it must first determine, through procedures set forth in the FHSA, that an article is a "hazardous substance" within the meaning of the FHSA. See U.S. v. Articles of Banned Hazardous Substances, 34 F.3d 91, 96 (2d Cir. 1994); Spring Mills, Inc. v. CPSC, 434 F. Supp. 416, 431 (D.C.S.C. 1977). A "hazardous substance" is defined as, *inter alia*:

> any substance or mixture of substances which (i) is toxic . . . if such substances or mixture of substances 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.

15 U.S.C. § 1261(f)(1)(A). However, the FHSA specifically exempts certain items, including pesticides, from the definition of "hazardous substances":

> The term "hazardous substance" **shall not apply to pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act** [7 U.S.C.S. § 136 et seq.] . . . but the term shall apply to any article which is not itself a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C.S. §§ 136 et seq.] but which is a hazardous substance within the meaning of subparagraph 1 of this paragraph by reason of bearing or containing such a pesticide.

15 U.S.C. § 1261(f)(2) (emphasis added). This provision, in effect, acknowledges that EPA will retain exclusive jurisdiction over the regulation of pesticides.

The petition also asserts that CPSC should ban CCA-treated wood pursuant to its authority under the Consumer Products Safety Act ("CPSA"), 15 U.S.C. §§ 2051 et seq. Like the FHSA, the CPSA also excludes pesticides from CPSC's jurisdiction. Under the CPSA, CPSC has limited authority to seek bans on hazardous "consumer products." However, "pesticides (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act)" are specifically excluded from the definition of "consumer product." 15 U.S.C. § 2052(a)(1)(D). Therefore, both the FHSA and CPSA exclude pesticides from CPSC's regulatory authority.

As discussed more fully below, CCA-treated wood is a pesticide under FIFRA and its implementing regulations[2] and, therefore, is excluded from the definition of "hazardous substance" in the FHSA and cannot be a "banned hazardous substance," nor can it be a "consumer product" within CPSC's regulatory authority under CPSA. See, e.g. Spring Mills,

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[2] EPA has made clear that treated wood, cutting boards, and other articles which are impregnated with a pesticidal chemical are not merely products which "contain" pesticides, but are themselves pesticides as defined by FIFRA. See infra note 7.

434 F. Supp. at 431. EPA has asserted broad jurisdiction over treated wood and other treated articles as pesticides under FIFRA; therefore, they are outside CPSC's jurisdiction. See 15 U.S.C. § 1261(f)(2).

A. EPA's Regulation of CCA-Treated Wood as a Pesticide Under FIFRA

For more than twenty years, EPA has actively regulated treated wood under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 et. seq., ("FIFRA"). This regulation has included use restrictions, application requirements, and data and safety reviews.

In 1978, EPA initiated a special administrative review process to consider whether the pesticide registrations for the uses of several wood preservatives, including the inorganic arsenicals, should be cancelled or modified. See 43 Fed. Reg. 48267 (Oct. 18, 1978). After six years of review, EPA determined that the use of arsenical wood preservatives, with certain restrictions, does not cause "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits. . . ."[3] See 49 Fed. Reg. 28666 (Jul. 13, 1984); see also FIFRA section 2(bb), 7 U.S.C. §136(bb). As part of this review, EPA conducted a "detailed assessment of the risks and benefits of continued registration of the wood preservative use of the inorganic arsenicals," and permitted the continued use and registration of CCA and other arsenicals as wood preservatives, with some modifications to the conditions of use. See 46 Fed. Reg. 13020 (Feb. 19, 1981); 49 Fed. Reg. 28666 (Jul. 13, 1984); 51 Fed. Reg. 1334 (Jan. 10, 1986); 53 Fed. Reg. 24788 (June 30, 1988).

As a result of this review, EPA imposed new regulations on CCA-treated wood. First, EPA imposed safety precautions for CCA applicators. 49 Fed. Reg. at 28673; 51 Fed. Reg. at 1338. Second, EPA established restrictions on uses of CCA-treated lumber. For example, CCA-treated lumber may not be used for cutting boards, counter tops, the portions of beehives which may come into contact with honey, animal bedding or structures, containers for storing animal feed or human food, or uses where it may come into contact with drinking water, except for incidental contact. Id. Third, EPA mandated general treatment standards, including the requirement that "processes used to apply inorganic arsenical formulations shall leave no visible surface deposits on the wood, as defined by AWPI Standard C-1 and AWPB Standards LP2 and LP22." 51 Fed. Reg. at 1338. In conjunction with EPA, the industry also established a voluntary consumer awareness program to instruct consumers on appropriate precautions to take when sawing or disposing of CCA-treated wood. Id. at 1337.

1. EPA Declares CCA-Treated Wood a Pesticide Under FIFRA

In 1988, EPA officially stated that it considers CCA-treated wood and other articles treated with pesticides to impart pest resistance to the article to be "pesticides" under FIFRA. See 53 Fed. Reg. 15952 (May 4, 1988), promulgating, inter alia 40 C.F.R. § 152.25(a). As part

[3] Contrary to the allegations in the EWG/HBN petition, EPA has never declared that the wood preservative uses of CCA posed "unreasonable risks to workers and nearby residents." See Petition at 2.

of a major package of revisions to its regulations implementing FIFRA, EPA issued a new section 152.25(a) which declares "treated articles" to be themselves pesticides, and, therefore, subject to regulation by EPA under FIFRA.[4] EPA's regulations implementing FIFRA define a treated article as a substance or article containing a pesticide if the purpose of the pesticide is to protect the substance itself and the pesticide itself is registered for such use. 40 C.F.R. § 152.25. CCA-treated wood clearly and unambiguously meets EPA's definition of a treated article, because the purpose of the pesticide treatment is to protect the wood itself from pests, mildew, and fungus. **Therefore, EPA has declared that CCA-treated wood is a pesticide, and is subject to regulation and registration under FIFRA, unless specifically exempted.** See, e.g. 40 C.F.R. § 152.25(a); 65 Fed. Reg. 7007 (Feb. 11, 2000) ("P.R. Notice 2000-1").

EPA has the authority to evaluate the level of FIFRA regulation appropriate for different pesticides. FIFRA section 25(b), 7 U.S.C. § 136w(b), authorizes EPA to exempt any pesticide from the requirements of FIFRA if EPA determines that the pesticide is not of a character requiring regulation under the statute. Under this authority, EPA has determined that treated articles that do not make claims regarding public health benefits, such as CCA-treated wood, may be exempt from FIFRA registration, if they meet certain conditions. In 1988 EPA issued a regulation implementing this policy that exempts "treated articles" "from all provisions of FIFRA when intended for use, and used, only in the manner specified." 40 C.F.R. § 152.25.

CCA-treated wood falls under the treated article exemption only if it meets certain regulatory conditions. First, the article must be treated with a registered pesticide. 40 C.F.R. § 152.25(a). Through the registration process, EPA obtains health and safety data related to that pesticide. The data required to support a registration are determined by the end use; in this way, EPA requires data on exposure and health effects of the end use of the registered pesticide – such as CCA-treated wood. In addition, registrants are under a continuing obligation to report adverse effects that are allegedly traceable to the pesticide. FIFRA § 6(a)(2). Second, the pesticide with which the article is treated must be specifically registered for that use, i.e. registered for treating the specific article or substance.[5] See, e.g. PR Notice 2000-1. Third, EPA has implemented

[4] By declaring treated wood to be a pesticide in the 1988 regulations, EPA clearly asserted jurisdiction to regulate aspects of treated wood that arose during its review of pentachlorophenol, creosote, and inorganic arsenicals; specifically, the 1988 regulation allowed EPA to prohibit the use of penta-treated wood indoors, prohibit the use of CCA-treated wood for certain uses, and require the use of registered pesticides to prevent applicators from making their own preservative formulations, thereby avoiding restrictions on uses of treated wood. See, e.g. 49 Fed. Reg. 28666; 51 Fed. Reg. 1334.

[5] EPA does not allow a pesticide registrant to merely indicate broad, general end uses for a given pesticide; rather, it requires registrants to state with specificity the types of articles into which the pesticide might be incorporated. 40 C.F.R. § 152.25, PR Notice 2000-1 ("EPA has not permitted broad general use patterns, such as the preservation of hard surfaces, plastics, adhesives or coatings for the registered pesticide. Instead, it has required that specific listings such as toys, kitchen accessories and clothing articles be reflected in the product registration and labeling as a prerequisite for incorporation of the pesticide into an article or substance under 40 C.F.R. § 152.25(a).")

specific rules for what claims may be made in marketing a treated article such as CCA-treated wood, and failure to comply with these rules will also cause the treated article to be considered an unregistered pesticide. See 63 Fed. Reg. 19256 (April 17, 1998); PR Notice 2000-1.

Therefore, according to EPA, a piece of treated wood is exempt from registration requirements only if it is properly treated with a registered pesticide,[6] the pesticide with which it is treated is registered specifically for the purpose of treating wood, and the product is marketed in accord with EPA guidance. Failure to meet any of these conditions will result in the treated wood itself requiring registration, including the FIFRA labeling of each piece of wood.

In general, CCA-treated wood products comply with EPA's conditions for the treated article exemption and are not separately registered. However, if a piece of CCA-treated wood fails to meet all the exemption conditions, it is subject to immediate enforcement action by EPA and must either comply with the exemption conditions or go through the registration process.

For example, in 1991, EPA took enforcement action against Columbia Cascade Company for offering for sale an unregistered pesticide – playground equipment made from treated wood. In the Matter of Columbia Cascade Co., Docket No. 1090-11-18-012 (EPA 1991) (complaint). EPA alleged that Columbia Cascade's "Interplay©" and "Columbia Cascade Play Equipment" catalogs offered for sale wood treated with NIEDOX-10, an unregistered pesticide. Id. at 2. EPA and Columbia Cascade reached a consent agreement which found that Columbia Cascade's sale of the treated wood playground equipment had violated FIFRA § 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A), and imposed a penalty. Id. EPA took separate enforcement action against the NIEDOX-10 manufacturer and applicator. See In the Matter of Pacific Wood Treating Corp., Docket No. 1090-11-17-012 (EPA 1991).[7]

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[6] Conversely, if wood is treated with an unregistered pesticide, EPA considers the wood itself to be an unregistered pesticide in violation of FIFRA. For example, EPA took enforcement action against Permapost Products Co., alleging that the company formulated ammoniacal copper zinc arsenate (ACZA) without a registration and used the unregistered ACZA as a wood preservative pesticide. See In the Matter of Permapost Products Co., Docket No. 1091-05-19-012 (EPA July 16, 1991). EPA alleged that Permapost's sale of the ACZA treated wood constituted a violation of FIFRA: "By selling and distributing ACZA treated wood ***which is an unregistered pesticide***, Permapost Products Co. violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), which prohibits selling or distributing a pesticide which is not registered." Id. (emphasis added).

[7] EPA has undertaken numerous other enforcement actions against treated articles that allegedly fail to meet the treated articles exemption. EPA takes the position that these products are themselves unregistered pesticides in violation of FIFRA. See, e.g. In the matter of Hasbro, Inc., Docket No. FIFRA 97-H-06 (EPA 1997) (alleging Playskool toys were unregistered pesticides); In the Matter of Courtaulds Coatings Inc., I.F. & R. No. 04-93F001-C (EPA 1992) (alleging that Portersept paint, which contained a pesticide, violated the labeling and advertising requirements for treated articles and was therefore an unregistered pesticide); In re Sears, Roebuck and Co., Docket No. I.F. & R. V 007-93 (EPA 1993) (alleging that Weatherbeater paint was an unregistered pesticide in violation of FIFRA due to claims made on its label, and noting

(Continued ...)

Therefore, EPA asserts that under FIFRA CCA-treated wood is a pesticide, but one that is *conditionally* exempt from FIFRA's registration provisions. It is *not* exempt from regulation. See 53 Fed. Reg. 15952 (May 4, 1988), promulgating, *inter alia* 40 C.F.R. § 152.25.

2. EPA's Regulation of CCA-Treated Wood

EPA's extensive regulation of CCA-treated wood is additional evidence that EPA views the treated wood as a pesticide within its jurisdiction. EPA has continually since the late 1970's required generation and submission of additional health, safety, and environmental effects data on CCA-treated wood. In 1986 the EPA Office of Pesticide Programs issued a special data call-in for arsenical wood preservatives, a procedure available to EPA under FIFRA. See U.S. EPA, "Special Data Call-In Notice on Wood Preservatives Containing Inorganic Arsenicals" (April 7, 1986) (Attachment 8). The Task Force responded to the data call-in by sponsoring approximately thirty scientific studies. See Summary of Studies (Attachment 9). The data developed includes studies on arsenic, copper and chromium – the active ingredients in CCA – and studies on treated wood. The data generated range from toxicology and ecotoxicology to leaching from treated wood to worker exposures.

EPA's most recent activities demonstrate the scope of its asserted regulatory authority over treated wood. Within the last few months, EPA has entered into a new agreement with industry to further promulgate consumer information about the safe handling of treated wood. See Letter from Marcia E. Mulkey, Director EPA Office of Pesticide Programs to Scott Ramminger, President and CEO of AWPI (June 29, 2001) (Attachment 10) (henceforth "June 29, 2001 Letter"). This program includes:

- an end-tag safety information label for CCA-treated lumber;
- new lumber bin stickers and signs;
- renaming the "Consumer Information Sheet" the "Consumer Safety Information Sheet," or CSIS, and including EPA-approved revisions;
- establishing a new 800 number for supplemental distribution of the CSIS;
- establishing a new Consumer Safety Information web site for supplemental distribution of the CSIS; and

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that "in that Weatherbeater is intended to prevent or mitigate the development of mildew, a fungus, Weatherbeater is a "pesticide" as that term is defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u); In the Matter of McNeil – PPC, Docket No. FIFRA 98-H-08 (EPA 1998) (alleging REACH© Toothbrush was an unregistered pesticide); In the Matter of Snow River Wood Products, Docket No. FIFRA 98-H-06 (EPA 1998) (alleging Sanatec carving board was unregistered pesticide).

- conducting a variety of programs to encourage retailer buy-in.

The enhanced program expands the end tag normally found on preserved lumber. For lumber 5/4" and larger, the new tags will contain basic safe handling information and a condensed version of the CSIS. Five basic safety messages are at the heart of the new label:

- Caution: Arsenic is in the pesticide applied to this wood.
- Never burn treated wood.
- Wear a dust mask and goggles when cutting or sanding wood.
- Wear gloves when working with wood.
- Ask for the safe handling information sheet or call 800-282-0600 or visit the website www.ccasafetyinfo.com.

In addition, stickers will be applied to the metal "arms" on lumber bins in retail stores and lumberyards and signs will be posted as well containing the five basic safety messages as described above for the new end tag.

The industry's toll-free number, 800-282-0600, provides supplemental distribution of Consumer Safety Information Sheets in English or Spanish. By dialing the number, callers can hear the CSIS in English or Spanish, and they can have it faxed to them in either language. The recorded message also provides information for contacting the National Pesticide Telecommunications Network to obtain additional information or to report a problem. Similarly, www.ccasafetyinfo.com contains the CSIS and links to the EPA web site and to the web site for the National Pesticide Telecommunications Network.

In addition, in May of this year, EPA informed the treated wood industry, including members of the Task Force, that it was instituting an expedited children's exposure risk assessment focusing on exposure to the preservative chemicals in playground equipment made from CCA-treated wood – exactly the subject before the CPSC today. See June 29, 2001 Letter; U.S. EPA, "Evaluating the Wood Preservative Chromated Copper Arsenate (CCA)" avail. at <http://www.epa.gov/pesticides/citizens/cca_evaluating.htm (noting that EPA is "conducting a focused assessment of the potential exposure of children to playground equipment built with CCA-treated wood" before "completing its comprehensive reregistration review") (Attachment 11). EPA's FIFRA Science Advisory Panel will review safety data on CCA-treated wood in October of this year. Thus, EPA is specifically addressing the very issue CPSC is considering whether to address in this petition. The Task Force is responding to EPA's concerns by sponsoring the development of additional scientific data and information specifically related to exposures to CCA from the use of CCA-treated wood in playground equipment. See infra section IV).

These actions are only the most recent examples of EPA's pervasive, ongoing regulation of CCA-treated wood under FIFRA, and EPA has made clear that it may further regulate the product in the event that the results of EPA's risk assessment demonstrate such regulation is necessary. See June 29, 2001 Letter ("Depending on the results of the risk assessment mentioned above, the Agency may find it necessary to request or require other actions, including regulatory actions"); U.S. EPA "Evaluating the Wood Preservative Chromated Copper Arsenate (CCA)" (describing pesticide review program as an opportunity for EPA to determine "whether changes are appropriate to ensure the safety of pesticides continued use").

In sum, EPA has officially declared that CCA-treated wood is a pesticide under FIFRA. It has exercised its authority to regulate virtually every aspect of the CCA wood treatment industry, including what pesticides may be used, who may apply it, how it is applied, how the treated wood product is marketed, and, most importantly, how the treated wood may be used. It is specifically examining the risks posed by chemical exposure from CCA-treated playground equipment, and has indicated that it will take regulatory action, if necessary.

B. Since CCA-Treated Wood Is a Pesticide Under FIFRA, CCA-Treated Wood Is Not a "Hazardous Substance" Within the Meaning of the Federal Hazardous Substances Act or a "Consumer Product" Within the Meaning of the Consumer Products Safety Act

As discussed above, the FHSA explicitly excludes certain product categories from CPSC's jurisdiction, including pesticides. The FHSA grants CPSC jurisdiction to ban certain hazardous substances, but provides: "the term 'hazardous substance' **shall not apply to pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act** [7 U.S.C.S. § 136 et seq.] . . ."15 U.S.C. § 1261(f)(2) (emphasis added). Similarly, "pesticides (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act)" are specifically excluded from the definition of "consumer product" in the CPSA. 15 U.S.C. § 2052(a)(1)(D).

EPA has already asserted its authority to regulate a treated article – such as a piece of playground equipment made from CCA-treated wood – as a pesticide. Under FIFRA's implementing regulations and EPA's interpretation thereof, any product impregnated with a pesticide that makes any claim that the product is protected against pests or will mitigate pests is ***itself*** a pesticide. Therefore, playground equipment, cutting boards, toothbrushes, toys, and other articles which make pesticidal claims and which are impregnated with a pesticidal chemical, or have components impregnated with a pesticidal chemical, are not merely products, which "contain" pesticides, but are themselves pesticides as defined by FIFRA. See supra note 7.

Because EPA, the expert agency in regulating pesticides and the agency that implements FIFRA, has determined that CCA-treated wood and any products made from CCA-treated wood are pesticides subject to FIFRA regulation, the pesticidal aspects[8] of treated wood and its uses are exclusively regulated by EPA and are outside CPSC's jurisdiction under FHSA and CPSA.

[8] This proceeding does not raise the issue of whether CPSC has the authority to regulate non-pesticidal aspects of playground equipment, such as CPSC requirements and guidance with respect to height, ground cover, and sizes of openings.

IV. Regulation of CCA-Treated Wood by CPSC Would Result in Confusing, Duplicative, and Possibly Inconsistent Regulation

In the FHSA and CPSA, Congress delineated the boundaries of CPSC jurisdiction, and granted EPA exclusive jurisdiction over the regulation of pesticides. The wisdom of this approach is illustrated by the potential for confusing and inefficient regulation if both CPSC and EPA assert jurisdiction over CCA-treated wood and its end uses. Regulation by both CPSC and EPA presents great potential for confusing, ambiguous, and potentially inconsistent regulation. In fact, there is evidence that the Environmental Working Group and the Healthy Buildings Network recognize EPA's jurisdiction, but are simply dissatisfied with EPA's regulatory choices and are therefore "forum shopping" by bringing this petition before CPSC. See EWG Press Release on CCA-Treated Wood Labeling Program ("This EPA is more interested in defending arsenic than it is in protecting the public, This is the second bad decision on arsenic by this EPA in the last six months") (Attachment 12); Healthy Building Network Press Release (July 3, 2001) (criticizing CCA-Treated Wood Labeling Program as "an arsenic cover-up" by EPA, "designed to distract attention from a vote by the Consumer Product Safety Commission to move forward a petition to ban arsenic treated wood from playground equipment") (Attachment 13). EPA has long regulated CCA-treated wood as a pesticide; CPSC should respect the intent of Congress and allow EPA to maintain exclusive jurisdiction.

Assertion of jurisdiction by both agencies will create an inconsistency in regulation. For EPA's regulatory purposes, treated articles such as CCA-treated wood are considered "pesticides" under FIFRA. For CPSC to assert jurisdiction, it would have to find that treated articles are ***not*** "pesticides" under FIFRA. This result would create widespread confusion in the industry and among the public as to the responsible regulatory authority. In addition, two federal executive branch agencies would be expressing contradictory and mutually exclusive positions. The federal government should speak with a unified voice regarding jurisdiction over CCA-treated wood and other treated articles.

This potential conflict applies not only to treated wood, but to all treated articles – the toys, toothbrushes, cutting boards, shower curtains or paints that make mildew resistance claims, and numerous other household products containing antimicrobials. EPA already has exercised its regulatory authority over these products, bringing enforcement actions against toys, cutting boards, and toothbrushes alleging violations of FIFRA regulations, including sale of unregistered pesticides. See supra note 7. For example, in 1997 EPA alleged that Hasbro, Inc.'s Playskool toys, including the Stack N'Scoop Whale, Roll N'Rattle Ball, and Animal Sounds Phone, were unregistered pesticides in violation of FIFRA due to improper marketing claims on the toys. In the Matter of Hasbro, Inc., Docket No. 97-H-06 (EPA 1997). As part of a consent agreement, Hasbro published new advertising for the toys in question. Id. EPA's actions make clear that it asserts regulatory jurisdiction over the pesticidal aspects of toys and other articles treated with pesticides.

CPSC and EPA should make clear to the regulated community and the public that all of the pesticide-related aspects of these "treated article" products are regulated by EPA exclusively. EPA's jurisdiction over all of these products statutorily excludes these same products from CPSC's jurisdiction. See 15 U.S.C. § 1261(f)(2). The prospect of CPSC jurisdiction over the pesticide-related safety of products made from treated wood creates confusion and the prospect of dual regulation not only for treated wood, but also for the increasing number of household products treated with pesticides. The pesticidal aspects of these products must be regulated by a single agency – EPA.[9]

EPA has long asserted jurisdiction over CCA-treated wood as a pesticide, and has considerable experience regulating it. It has 25 years of experience evaluating data on the safety of CCA-treated wood. EPA already has imposed many regulations on various aspects of CCA-treated wood, including its permissible end uses. Under FIFRA, EPA can impose additional regulations or restrictions on CCA-treated wood and its uses, if it finds that this is necessary. The FHSA, the CPSC and the interests of regulatory efficiency demand a determination that EPA has sole regulatory jurisdiction over treated wood and its uses.

V. Data Show that Exposure to CCA-Treated Wood Does Not Pose an Unreasonable Risk to Children

As discussed above, CCA-treated wood and its end uses are comprehensively regulated by EPA under FIFRA. Nevertheless, the Commenting Trade Associations are pleased to discuss the scientific data on CCA and CCA-treated wood, including risk assessments, with CPSC.[10] The following sections discuss the sizable amount of data on the health effects of exposure to CCA-treated wood. These data demonstrate there is no unreasonable risk to children or the general public from the use of CCA-treated wood. First, this section points out misinterpretations of scientific data in the petition and how these misinterpretations impact the evidence of potential risk to children from CCA-treated wood (Subsection A). Second, it identifies factors to be considered in assessing the risk to children from CCA-treated playground equipment (Subsection B). Third, it explains how even using conservative assumptions, there is no unreasonable risk to children from CCA-treated wood playground equipment (Subsection C).

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[9] Even if the CPSC determines that it has jurisdiction over CCA-treated wood playground sets under the FHSA, the Commission could exempt CCA-treated wood playground sets from the FHSA's requirements because CCA, CCA-treated wood, and CCA-treated wood playground sets are already subject to extensive regulation under FIFRA. The FHSA provides:

> The Secretary [Commission] may exempt from the requirements established by or pursuant to this Act any hazardous substance or container of a hazardous substance with respect to which he [it] finds that adequate requirements satisfying the purposes of this Act have been established by or pursuant to any other Act of Congress.

15 U.S.C. § 1262(d). As discussed above, EPA has been actively regulating CCA-treated wood and its end uses for more than 25 years.

[10] All of the data and studies discussed below have already been submitted to EPA.

A. The Petition Misinterprets Much of the Data as Applied to CCA-Treated Wood, and, Thus, the Potential Risk

In several instances, the petition misinterprets or misrepresents data that are not directly applicable to a risk assessment of CCA-treated wood. The following sections explain these misinterpretations and their impact on the assessment of potential risk from CCA-treated wood.

1. The Petition Does Not Differentiate Among Valence States, Which is Critical to Toxicity

The petition does not differentiate among compounds of arsenic with regard to the arsenic valence state, arsenic species, or between organic arsenical and inorganic arsenical compounds. The species and/or form of arsenic influences physical and chemical properties such as physical state and water solubility, as well as biological properties, thus influencing toxicity. Consequently, data for one form of arsenic may be of limited relevance to another form. For example, the trivalent inorganic form of arsenic is more toxic than the pentavalent inorganic form, and both of these are more toxic than organic arsenicals. There is a 300-fold difference in mouse acute oral toxicity values between arsenic trioxide and trimethyl arsine oxide. See Yamauchi, H. and H. Fowler, "Toxicity and Metabolism of Inorganic and Methylated Arsenicals" in Arsenic and the Environment, part II, J. Nriagu, ed., p. 44 (1994). The most toxic form of arsenic, for example, is arsine, a trivalent inorganic gas. The studies which provide the basis for the toxicological criteria of arsenic primarily involve highly soluble arsenate and arsenite in drinking water. These differences have relevance to the toxicity of arsenically-treated wood, as explained below, and are completely overlooked in the petition.

2. The Petition Incorrectly Equates Exposure to CCA-Treated Wood with Exposure to Arsenic

The petition equates risk from CCA-treated wood with inorganic arsenic. This is incorrect. As explained above, when wood is pressure treated with CCA, chemical fixation reactions occur between the components of CCA preservative and the wood. The results of the reactions yield a stable complex of chromium, arsenic and copper with wood carboxylates predominantly in the wood cell wall. The "fixation" reaction process renders the CCA components strongly "fixed" to the wood thereby conferring preservative property to the wood. See supra section I.B.2. Forest Products Society (1995). The mechanism of these reactions has been the subject of much research, recently summarized by D. C. Bull. See Bull, D.C., "The Chemistry of Chromated Copper Arsenate II: Preservative Wood Interactions, Wood Science and Technology" (2001).

The work reported by Bull as well as work reported by Kamdem of Michigan State University and research completed by the Research Division of Osmose Wood Preserving Company demonstrate that once fixed with wood cellulose, the chromium, copper and arsenic metals of CCA exist predominantly as water-insoluble complexes with other organic and inorganic components of wood. See Kamdem, D.P., Unpublished report, "ESEM of CCA Type C Treated Southern Pine" Department of Forestry, Michigan State University (undated) (Attachment 14); Kamdem, D.P. and W. Cui, Unpublished report, "X-Ray Diffraction of CCA Treated Wood Surface" Department of Forestry, Michigan State University (undated)

(Attachment 15); Osmose Research Division, Unpublished report, Surface Chemical Analysis of CCA Treated Southern Pine Lumber, Osmose Wood Preserving Division, Buffalo, NY (2001) (Attachment 16). This was specifically demonstrated for CCA-treated wood surface deposits. See Kamdem; Kamdem and Cui; Osmose. These investigations showed that:

1) X-ray diffraction analysis of CCA solution is different from samples of the surface of CCA-treated (and untreated) wood indicating that CCA treatment did not promote the formation of crystals on the surface of the treated wood (Kamdem and Cui);

2) CCA-treated and untreated wood surfaces subjected to scanning electron microscopy showed that solids presents on the wood surface were amorphous complexes of oxygen, carbon, calcium, chromium, copper, arsenic and iron and that the deposits on CCA-treated wood surfaces were calcium, arsenic, copper and iron combined with oxygen, and that the solid deposits did not contain arsenic pentoxide or arsenic trioxide (Kamdem);

3) the surface residue on CCA-treated wood is less than 0.5% copper, arsenic or chromium and of that 0.5% only about 10% of the arsenic on the surface of the treated wood (<0.05) is water-soluble (Osmose).

As explained above, the chemical form of arsenic as it exists in CCA-treated wood (sawdust) and on CCA-treated wood surfaces as dislodgeable residue is not equivalent to soluble arsenate and arsenite. Because of this, the chemical/physical and toxicological properties of the arsenical compounds from CCA-treated wood are different from arsenic species in water. A demonstration of this difference can be found in toxicological studies in mammals completed with CCA-treated wood.

For example, S.A. Peoples and H. R. Parker fed beagle dogs CCA-C wood dust using Southern pine treated wood. See Peoples, S.A. and H.R. Parker, "The Absorption and Excretion of Arsenic from the Ingestion of Sawdust of Arsenical Treated Wood by Dogs," unpublished report, University of California-Davis (1979) (Attachment 17). The dog's daily dose of wood dust was approximately 2g/13 Kg, or about 0.15g/Kg for a 13 Kg dog. Drs. Peoples and Parker measured the amount of arsenic the dogs consumed on a daily basis as 6000µg/day from treated wood and 135µg/day from standard lab chow, or 6.1 mg arsenic/day. Feedings continued for eight consecutive days, for a total wood dust dose of 1.2g/kg equating to about 49mg arsenic (as the element)/Kg. This dosing scheme equates to approximately 0.47 mg As/Kg/day or 3.8 mg As/Kg total dose over the course of the study. There were no adverse clinical signs noted during the eight-day dosing period. Urinalysis, serum chemistry and hematology values were unchanged as a result of dosing. Since Peoples and Parker examined feces prior to dosing with CCA-treated wood and found no arsenic at a level of detection of 1µg/sample, they assumed that fecal arsenic found during feeding of treated wood represented unabsorbed arsenic. About 60% of the ingested arsenic was found in the feces and 40% of the arsenic ingested was excreted in the urine. Since arsenic in the feces is not metabolized, this means that the bioavailability of arsenic from CCA-treated wood ingestion was about 40% in this study. The majority of the urine arsenic was dimethyl arsenic and no trivalent arsenic was detected.

Peoples conducted a higher dose study in which he fed dogs 10g of CCA-treated wood dust daily for five days to yield a daily dose of 39 mg arsenic, or about 3 mg arsenic/Kg/day. See Peoples, S.A., "The Amount and Valence or Arsenic in the Urine of Dogs Fed CCA-C in Their Diet," unpublished report, University of California-Davis (Attachment 18). The dogs demonstrated no signs of toxicity during treatment. Fecal excretion varied from day to day, ranging from 23 to 100%. The average amount of dosed arsenic excreted in feces during dosing was approximately 74%; the average amount of arsenic excreted in urine during dosing was 16.5%, again indicating a low bioavailability of arsenic from ingesting treated wood. In this study pentavalent arsenic was found in the urine along with dimethyl arsenic.

The table below puts these study results into perspective. Peoples fed dogs CCA-treated wood sawdust that contained amounts of arsenic, which, if given in pure form, would likely be lethal to dogs and humans. See Garcia-Yargas, G. and M. Cebrain, "Health Effects of Arsenic" in Toxicology of Metals, Louis W. Chang, ed. P. 424, CRC Lewis Publishers, New York, 1996. The health of the dogs, however, was unaffected, and all of the arsenic was excreted in feces or urine. This was possible because the form of the arsenic in the wood was not soluble inorganic arsenic, thus reducing the bioavailability of the arsenic in the wood dust.

Inorganic Arsenic vs. CCA-Treated Wood: Acute Oral Toxicity

Material Ingested	Amount of Arsenic Ingested as Elemental Arsenic	Response	Reference
Arsenic trioxide (Arsenite)	53 – 136 mg or 0.96 – 2.8 mg./Kg in a 55 Kg person	Human lethality	Garcia-Vargas & Cebrian, 1996
Arsenic Pentoxide (Arsenate)	2 mg/Kg	Dog lethality	ATSDR, (1993)[11]
CCA-Treated Wood Dust	3 mg/Kg/day for 5 days	No effect in the dog	Peoples, undated

Dr. Peoples also investigated the potential for transdermal absorption of arsenic from CCA-treated wood dust contact with skin. See Peoples, S.A., "The Dermal Absorption of Arsenic in Dogs from Sawdust from Wood Treated with ACA and CCA-C," unpublished report, University of California-Davis (1979) (Attachment 19). In this study, a Beagle dog had 1.5g of wood dust (about 45mg As) applied under a patch to clipped skin continuously for two days. Peoples was able to detect background levels of dimethyl arsenic in the urine prior to wood dust application, and found no increase in urinary excretion of organic arsenic (dimethyl arsenic) during the application period (no other species of arsenic were detected in the urine).

[11] ATSDR, Toxicological Profile for Arsenic, Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, 1993.

A University of Alabama study which used pregnant rabbits dermally exposed to CCA-C sawdust for days 7-20 of their pregnancy similarly provided no evidence of any treatment-related effect in the rabbits. See Hood. R. A., Evaluation of Chromated Copper Arsenate (CCA) Impregnated in Sawdust For Teratogenicity and Maternal Toxicity in Mice and Rabbits. Unpublished report, University of Alabama, (1979) (Attachment 20). The pregnant animals received 26g of CCA-treated wood dust on days 7, 11, and 15 of gestation. The test material remained on the skin under vinyl plastic film until gestation day 20. Maternal response to dermal dosing stress was equivalent in treated and control groups. According to the author of the study, there was no differences between the treated and control groups in gross, skeletal, or visceral malformations, indicating that extended dermal exposure to CCA-treated wood dust is not teratogenic or fetotoxic. It is noteworthy that the skin of rabbits is considered to be more susceptible to chemical permeation than human skin, thereby making the rabbit an overpredictor of dermal penetration.

Hood also tested pregnant mice with dietary exposure to 10% CCA-treated wood sawdust or untreated wood dust. See Hood, (1979). A control group was employed that received lab chow and no wood dust. Maternal arsenic exposure via dietary admixture of CCA-C sawdust and lab chow throughout pregnancy (gestation days 1-18) produced no effect on maternal weight gain and no effect on fetal parameters including fetotoxicity, and skeletal or visceral malformation when compared to untreated wood dust or no wood dust exposure.

In vivo cytogenetics studies have been completed in mice receiving dietary exposure to CCA-C wood dust for up to 21 days. See Graham, B.Y., "In Vivo Cytogenetics Studies of Chromated Copper Arsenate Treated Sawdust in Mouse Bone Marrow," unpublished report, University of Alabama (1979) (Attachment 21). Fifty metaphase plates (minimum 1000 mitotic figures) were scored for each animal (3/group). No changes were observed in chromosome number or structure (chromosome damage, breaks or chromatid breaks) in treated (CCA-C) verses control groups (untreated wood and no wood). In the same study, blood cell parameters (red cell count, white cell count and white cell differential count, hemoglobin and hematocrit) were examined and found to be unaffected by 21 days of oral gavage with CCA-C sawdust (2500mg/kg/day). See Graham, (1979).

The following table summarizes the disparate results of studies on toxicity of arsenic versus CCA-treated wood:

Inorganic Arsenic vs. CCA-Treated Wood: Repeated-Dose Oral Toxicity

Study Design; Material Ingested	Amount of Arsenic Ingested as Elemental Arsenic	Response	Reference
Mouse Developmental Toxicity; Arsenic pentoxide	10 mg As /Kg /day = NOAEL in mice Days 6-15 of gestation; 32 and 64 mg/Kg/day were effect levels	Maternal death, embryotoxicity	Nemec, 1988[12]
Mouse Developmental Toxicity; 10% CCA-Treated wood dust in diet	100mgAs/Kg/day*	No maternal toxicity, no embryo or fetal toxicity	Hood, 1979
Mouse In vivo Cytogenetics; Arsenic trioxide (Arsenite)	50 mg/kg/day	Positive for micronucleus effects	Tinwell, 1991[13]
Mouse In vivo Cytogenetics; 10% CCA-Treated wood dust in diet	100 mg As/Kg/day for 21 days	No chromosomal effect	Graham, 1979a

* Assumptions for dose calculation: 30 g (0.03 Kg) average body weight of female mouse during dosing and 5 g/day feed consumption. Arsenic content of CCA-treated wood sawdust = 3000μg As/ 1000 mg CCA-treated wood dust.

As illustrated by the previous table, when matched by test animal species and endpoint, these studies demonstrate a marked reduction in general toxicity and specific toxicological endpoints, including the developing fetus, for CCA-treated wood versus inorganic arsenic. Again, this is possible because arsenic in CCA-treated wood is not free inorganic arsenic, and because the bioavailability of the arsenic in wood dust is greatly reduced.

Unpublished case reports of pets, cattle or other livestock ingesting or cribbing (chewing) CCA-C treated wood have been circulated. Unfortunately, in most instances, no objective findings accompany the reports, and the reports remain unsupported assertions of CCA-C treated wood toxicity. When professional investigation of a report has been performed by a local veterinarian or university animal hospital and lab, metal toxicity of any sort has usually been ruled out (for example, viral death in cats, or garden plant pesticide poisoning in dogs is often suspected to be the cause). Heavy metal toxicity, including from arsenic and lead, has been

[12] Nemec, M., "A Teratology Study in Mice with Arsenic Acid (75%)," WIL Research Laboratories (1988) (unpublished study submitted to USEPA under FIFRA EPA MRID No. 406462-02).

[13] Tinwell, H., et al., Environmental Health Perspectives 95:205 (1991).

discovered in some instances. However, the absence of any elevated level of chromium or copper in animals with toxic arsenic levels strongly suggests that the source of the arsenic was other than CCA-C wood. Of the three metals in CCA-C treated wood, arsenic is excreted the quickest, so the finding of arsenic in a poisoned animal would be accompanied by elevated levels of copper and chromium in that animal if the source of the metals was CCA-C treated wood.

3. Contrary to the Assertions of the Petition, Data Do Not Indicate That Exposure to CCA-Treated Wood Results in Greater Risk Than Previously Recognized

The petition points to the National Research Council Report on Arsenic in Drinking Water (NRC) position that arsenic is a more potent carcinogen than previously recognized and that human lung and bladder cancers may be caused by arsenic in addition to skin cancer. See National Research Council (NRC), Arsenic in Drinking Water, National Academy Press, (1999). The underlying evidence for this comes from reanalyses of the Taiwanese, Chile and Argentina drinking water studies. The petition also cites the NRC report to assert that arsenic exposure contributes to the development of noncancer diseases such as immune suppression, hypertension, cardiovascular disease and diabetes.

The arsenic epidemiology studies completed on the arsenic-exposed populations of Taiwan, Chile, and Argentina have, themselves, been the subject of reviews and reanalysis by a score of researchers. The NRC report acknowledges that few data address the degree of cancer risk at oral exposures lower than those studied in the Taiwanese, Chile and Argentina drinking water studies. Population exposure to arsenic in these studies was to drinking water containing <100 to over 600 μg/L arsenic. The data most often cited come from the studies of the regions of Taiwan with contaminated drinking water wells. It is important to note that a recent epidemiological study conducted in the U.S. found no convincing evidence of increased cancer in individuals exposed to arsenic in drinking water at levels up to 166 mg/l on average. See Lewis, D.R., J.W. Southwick, R. Ouellet-Hellstrom, J. Rench, & R.L. Calderon, "Drinking Water in Utah: A cohort mortality study" Environ. Health Perspectives 107:359-365 (1999).

Stohrer has also reviewed the arsenic epidemiology data and concluded that 400 μg/day is safe. See Stohrer, G., "Arsenic: Opportunity For Risk Assessment," Arch. of Toxicology, 65, 535-531, (1991). Stohrer bases this conclusion on the Tseng studies of Taiwan, a follow-up study by Chen that addressed bladder and lung cancer in addition to the skin cancers seen by Tseng, and a 1988 study from Bengal. See Tseng, W.P. "Effects and dose response relationships of skin cancer and blackfoot disease with arsenic," Environ. Health Perspectives 19:109-119 (1977); Chen, C. J., et al., "Arsenic and Cancers," The Lancet, 414-415 (1988); Guha Mazumder, D. N., et al., "Chronic Arsenic Toxicity From Drinking Tube Well Water in Rural West Bengal," WHO 65, 499-506, (1988). In his analysis of these studies, Stohrer concludes that:

1. More than 400 μg arsenic daily is required to cause arsenical disease;

2. Skin cancers, internal cancers and non-cancerous effects of arsenic all have the same threshold dose and probably result from the same primary interaction;

3. Hyperpigmentation can therefore serve as a sensitive indicator of arsenic exposure and of future cancer risk;

4. Synergistic interactions change the log-normal dose response slope, but leave unchanged the intercept or the threshold dose.

The studies cited by NRC regarding cardiovascular effects are studies of high-exposure populations, see Tseng, (1977) and Chen, (1990), as are the studies reporting peripheral vascular disease. See NRC, (1999). The human data base for immunosuppressive effects of arsenic is derived from populations exposed to arsenic in drinking water (> 400 μg/L), or from Fowler's patients, (individuals who consumed Fowler's Solution, an inorganic arsenical, and received a daily dose of 5-10 mg As/day for up to 12 years). See Gonsbatt, et al. "Lymphocyte Replicating Ability in Individuals Exposed to Arsenic in Drinking Water," Mutat. Res., 313, 293-299, (1994). Hypertension has been associated with arsenic toxicity secondary to liver damage and has been reported in the studies of the Taiwanese cohorts and the Fowler's cohort. Together, these responses to chronic overexposure to inorganic arsenic are linked by 1) the very high doses of arsenic the individuals received, and 2) what Wang and Rossman (1996) cite as the threshold for arsenic effects. Wang, Z. and T. Rossman, "The Carcinogenicity of Arsenic" in Toxicology of Metals, Louis W. Chang, ed., CRC Lewis Publishers, (1996).

As shown by the exposure discussion in Subsection B, children or adults playing on or otherwise using CCA-treated wood will not receive an arsenic exposure that exceeds any demonstrated threshold for adverse effects, particularly the effects listed in the Environmental Working Group/Healthy Building Network Petition.

4. Contrary to the Assertions in the Petition, There Are No Reliable Data that CCA-Treated Wood Is Associated with Endocrine Disruption

The petition asserts that arsenic is an endocrine disruptor and exposure to CCA-treated wood may be associated with endocrine disruption. The petition cites Kaltreider, et al, and states that these researchers found that 25-50 μg arsenic/L in water produces endocrine disruption. See Kaltreider, R.C., et al., "Arsenic Alters the Function of the Glucocorticoid Receptor as a Transcription Factor," Environ. Health Perspectives, 109:3, 245-251 (2001). However, as discussed in the following paragraphs, the cited study provides no support for the allegation of endocrine disruption.

Kaltreider's group tested sodium arsenite *in vitro* on the activity of the glucocorticoid receptor at concentrations of 24.7–247.5μg arsenic/L. Effects were reported for only at the highest concentration tested, a dose level 10-fold greater than the concentration cited in the petition. This research is not relevant to human arsenic hazard assessment because it fails to account for the unique pharmacokinetics of arsenic in the rat. Moreover, it does not fall within the Endocrine Disruptor Screening and Testing Advisory Committee's (EDSTAC) finding on the scope of endocrine disruptor effects that can be assessed, given the current level of endocrine science. U.S. EPA Office of Prevention, Pesticides, and Toxic Substances, "Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) Final Report" (1999), at ES-2 –3 and 3-6.

Kaltreider reports on *in vitro* experiments which examined the effect of sodium arsenite (an inorganic trivalent form of arsenic) on cultured H411E rat liver hepatoma cells. In justifying the choice of cultured rat liver tumor cells, the investigators assert that "the liver represents a relevant biological target of arsenic exposure because it is a first pass organ and is directly associated with various arsenic-related human disease states such as diabetes and cancer." The investigators did not, however, report on the metabolic capacity retained by the liver cell line used in their experiments, specifically on H411E cell glutathione levels (GSH), and did not account for the unique pharmacokinetics of arsenic in the rat. These are important omissions because each is a key factor in the metabolism, and, therefore, detoxification of arsenic. The metabolism of inorganic arsenic in mammals involves methylation as key biotransformations. See Vahter, M., "Species Differences in the Metabolism of Arsenic" in Arsenic Exposure and Health, W.R. Chappell, C.O. Abernathy, and C.R. Cothern, eds., pp. 171-180, Science and Technology Letters, Northwood (1994). Methylated arsenic metabolites are less acutely toxic than inorganic arsenic and "considerably less reactive with tissue components." Methylation occurs predominantly in the liver following oral exposure to arsenic and involves transfer of a methyl group to arsenic from S-adenosylmethionine. The reaction requires glutathione (GSH). Depletion of GSH decreases methylation and increases inorganic arsenic toxicity. Since factors which influence methylation can influence arsenic toxicity, the metabolic capacity of the H411E rat liver cells used by Kaltreider, especially the GSH level of those cells during incubation with arsenic trioxide, is a crucial factor in the arsenic response measured by Kaltreider. If uncontrolled, this factor could lead to an outcome observed *in vitro* with little or no relevance to an *in vivo* exposure.

Equally important, the Kaltreider research is outside the endocrine systems which EDSTAC found were adequately studied to permit assessment of potential endocrine disruption effects. EPA formed EDSTAC to design screening and testing programs to assess endocrine effects and to provide a scientific framework for decisionmaking using the data. EDSTAC, as part of its work, reviewed the current ability of the science of endocrine disruption and determined that work should focus only on estrogen, androgen and thyroid effects at this time, and that work on other system be delayed until "more data become available on other hormones, and assays are developed to identify effects on them." EDSTAC Report at ES – 3.

The work of Kaltreider does not involve the estrogen, androgen or thyroid hormone receptor. Kaltreider reports on the glucocorticoid receptor, a receptor like the estrogen and androgen receptor found in the cytoplasm of the cell and responsive to steroid hormones, but a receptor family that responds to cortisol and corticosterol, not estrogen or androgen (or thyroid hormone). In contrast, the EDSTAC recommendation that EPA revisit the state-of-the-science as new test methods become available reflects its lack of confidence in current testing methodologies to adequately assess hormone-mediated effects other than those of sex hormones and thyroid hormone. There has been no change in this position by EPA or EDSTAC.

EDSTAC also provided principles for evaluating tests and test data employed in assessment of potential endocrine disrupting substances, concluding that "*in vitro* assays cannot constitute a decision mode." They are useful as information on possible mechanisms (or site of action) but not as yes/no determinants to proceed to *in vivo* screens or upper tier testing. EDSTAC also stated that results from *in vivo* assays have more weight than results from *in vitro* assays because "*in vitro* assays will generate false negatives as well as false positives, based on differences in access to the target tissue, metabolism, etc., relative to *in vivo* assays." EDSTAC Report at 5 – 39. The EDSTAC findings clearly show the fallacy of using the results from a single test, most particularly an *in vitro* test, to make a determination of the potential for a material to act as an endocrine disruptor.

5. Contrary to the Assertions in the Petition, There Are No Reliable Data that Children Are More Susceptible to Exposure to CCA-Treated Wood

The petition cites the National Research Council Report on Arsenic in Drinking Water (NRC) to state that children metabolize arsenic differently than adults, i.e., more slowly, and that people with poor nutrition may be more susceptible to arsenic related health effects. The NRC citation for this a 1998 paper by Concha, et al. published in Environmental Health Perspectives See Concha, et al., Environ. Health Perspectives, 36:6, 355-359, (1998). This paper describes blood and urinary arsenic levels in children and women of three villages in Argentina. Two of the villages had drinking water heavily contaminated with arsenic from geologic origin (200μg/L) and the third village had drinking water containing <1 μg/L arsenic. The drinking water from each of the villages contained <2μg/L selenium, ruling out selenium antagonism of arsenic toxicity. The study included 36 children and 27 women from the two arsenic-contaminated villages and 21 children and 12 women from the non-contaminated villages. Blood and urine arsenic levels were measured in the study cohorts, and from the exposed villages the average arsenic concentration was 9μg/L for blood and 350 μg/L for urine, the highest ever recorded for children according to the study author. These values did not differ significantly between the children from the two exposed villages and were 10-times higher (for blood arsenic) and 30-times higher (for urinary arsenic) than the concentrations of women and children at the non-contaminated site. There was little or no influence of age or sex on these concentrations within villages. Despite these high arsenic exposures, the authors reported that there were no signs of chronic arsenic toxicity (palmo-planar hyperkeratosis, pigmentation changes, or skin cancer) observed by the local physician in the first village, but that such signs were observed in the population of the second village including in children. The authors confirmed signs of arsenic toxicity in one child and one adult of the second village in the study. The study did not indicate increased frequency of toxicological effects in children versus adults.

The authors reported that even though the urinary total arsenic concentrations did not differ by age or sex, the proportion of fully metabolized arsenic (dimethyl arsenic, DMA) in the children's urine was lower than that of the adult women. The authors also pointed out toxicological implications to this difference: that DMA is less reactive toxicologically than inorganic arsenic. These observations form the basis for the claim that there may be differences in how children metabolize arsenic and that children may be more susceptible than adults to arsenic. The authors note that differences between children and adult urinary arsenic metabolites, like those seen in their study, have not been consistently reported. The authors suggest that a genetic polymorphisms exists in the population for S-methyltransferases, the enzymes responsible for inorganic arsenic metyhylation and that this may account for metabolic differences between populations of the same age.

Examination of the Concha data show that the difference between adult and children's urinary DMA levels was seen in only one of the two arsenic exposed populations. The distribution of the urinary arsenic metabolite values are not provided in the publication, but the authors state that in the village where a metabolite pattern difference was observed, 6 of the 24 children in the study had urinary inorganic arsenic concentrations over 60%. The table below is reproduced from the Concha publication and provides the urinary metabolite data used to support the claim of age differences in arsenic metabolism.

Median Concentration of Urinary Arsenics in Women and Children of Villages With Arsenic Contaminated Drinking Water (from Concha, 1998)

Village	Urinary Arsenic Metabolites		
	% Inorganic Arsenic	% Monomethyl Arsenic	% Dimethyl Arsenic
Village 1 – Children	49 (21 - 76)	3.6 (0.9 - 12)	47 (22 – 68)
Village 1 – Women	25 (8.5 - 42)	2.1 (0.8 - 8.3)	74 (55 – 93)
Village 2 – Children	42 (26 - 54)	3.4 (1.3 - 7.9)	54 (44 – 88)
Village 2 – Women	39 (18 - 52)	2.2 (1.1 - 3.5)	58 (48 – 80)

Only the data for Village 1 shows a difference between children and adult women urinary arsenic metabolites. It is unknown how much of this difference is due to the 6 children with urinary inorganic arsenic levels above 60%. The urinary metabolite pattern in Village 2 is equivalent between children and adults. The authors do state there is considerable interindividual variation in arsenic methylation capacity. They also point to the limited number of other studies that investigated urinary arsenic metabolite speciation and state that some of the reported variation is due to analytical variation and that adequate quality control has not always been reported for urinary arsenic metabolite determinations. They cite a 1997 study of interlaboratory comparisons of human urinary arsenic metabolite determination which showed "extensive variation in the results." See Crecelius, E. and J. Yeager, "Intercomparison of Analytical Methods for Arsenic Speciation in Human Urine," Environ. Health Perspectives, 105, 650-653, (1997). The authors do not explain why there would be a different response to urinary arsenic metabolite formation in children of equal arsenic exposure (Village 1 and Village 2 had equivalent aresnic drinking water exposure) except to suggest methyltransferase polymorphism. The Concha article did point out that despite the very high levels of arsenic exposure and the purported sensitive population of children, there were no observations of arsenic toxicity in Village 2. There was, however, an estimate by the authors of a 12% malnourishment rate in the children of the first village. The overall health status of the children is not reported. Given the very high levels of arsenic exposure and the correspondingly high body burden of arsenic measured in the children of both exposure villages, it is a possibility that rather than methyltransferase polymormism, the children have a nutritional glutathione deficiency (GSH) and/or underlying liver disease resulting in the inability to adequately methylate the high oral doses of arsenic they are receiving daily in their food and water. According to Buchet and Lauwerys writing on human metabolism of inorganic arsenic, "the rate limiting step (for the metabolism of inorganic arsenic) is the first methylation reaction which is facilitated by the presence of reduced glutathione; the second methylation reaction appears very efficient but is easily inhibited by an excess of inorganic arsenic." See Buchet, J. P. and R. Lauwerys

"Inorganic Arsenic Metabolism in Humans" in Arsenic Exposure and Health. W. R. Chappell, C. O. Abernathy and C. R. Cothern, eds., pp181-189, Science and Technology Letters, Northwood, (1994).

A glutathione deficiency in Village 1 children could produce the same pattern of urinary arsenic metabolites observed by Concha and could account for the observations reported by that team. Such a situation would be an unfortunate human correlate to the observations Peoples made in the dog studies in which some inorganic arsenic was found in the dog urine at the high CCA-treated wood doses (unlike lower doses) because the very high doses yielded enough inorganic arsenic to overwhelm the dog methylation capacity, even in the absence of signs of toxicity. Given the small number of children studied by Concha and the very high arsenic exposures (200µg/L) the children received[14] the existence of polymorphism at the methyltransferase gene loci is not a confirmed hypothesis. Moreover, there is no convincing evidence of any increased toxicological sensitivity of children to arsenic.

B. Children's Exposure to Arsenic from CCA-Treated Wood Is Negligible

There are two primary sources of possible exposure to arsenic for children at playgrounds with CCA-treated wood equipment: 1) arsenical compounds from the wood that have leached into the soils; and 2) dislodgeable arsenical compounds from the equipment. See Exponent, Inc., "Technical Issues Associated with the Risk Assessment of Children's Exposure to Arsenic at Playgrounds Structures Constructed from CCA-Treated Wood," (2001) (hereinafter "Exponent Technical Report"). For each of these sources there are two potential pathways for exposure – dermal and ingestion. Inhalation exposure is not considered to be a significant exposure route for playground and residential exposure scenarios.[15] A careful review of the

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[14] Children living near known industrial arsenic sources in the US (cadmium refineries, copper and lead smelters) have average urinary arsenic concentrations are below 20µg/L; in children without known environmental arsenic exposure the urinary arsenic values are 5-10µg/L (cited in Concha, (1998)).

[15] Dislodgeable arsenic is not volatile and no release mechanism exists during normal playground or residential use of CCA-treated structures that would generate significant quantities of respirable wood particulate. See Gradient Report, Exponent Technical Report, *infra* Section V.C. Exposure to resuspended soil particulate that has been impacted with arsenic originating from CCA-treated structures also is not considered a significant exposure pathway based on soil exposure assessment studies by HS & WMR, (2001a), Cohen et al., (1998), and Polissar et al., (1990) in which inhalation of resuspended soil was determined to be an insignificant exposure pathway for arsenic. Hazardous Substance & Waste Management Research, Inc. (HS&WMR) "Health Considerations Related to Arsenic in Soil Under Decks Constructed of CCA-Treated Wood (Draft)" prepared for Scientific Certification Systems (2001a); Cohen, J.T., B.D. Beck, T.S. Bowers, R. L. Bornschein, and E.J. Calabrese "An arsenic exposure model: Probabilistic validation using empirical data," Human Ecol. Risk Assess. 4(2):341-377 (1998); Polissar, L., K. Lowry-Coble, D.A. Kalman, J.P. Hughes, G. van Belle, D.S. Covert, T.M. Burbacher, D. Boligiano, and N.K. Mottet "Pathways of human exposure to arsenic in a community surrounding a copper smelter," Environ. Research 53:29-47 (1990).

available data shows that children's exposure to arsenic from treated wood is less than other environmental exposures and unlikely to pose unreasonable risks.

1. Available Data Show that Release of Dislodgeable Arsenic From Play Structures Diminishes Over Time

Studies of dislodgeable arsenic from fresh and weathered treated wood indicate that weathered treated wood yields less dislodgeable arsenic than freshly treated wood. See Scientific Certification Systems (SCS) "Study of Arsenic Leaching into Soils Underneath CCA Treated Wood Decks," Commissioned by Osmose, Inc. (1998); Solomon, K.R. and J.E. Warner "Persistence, Leaching, and Bioavailability of CCA and Pentachlorophenol Wood Preservatives," Interim Report 4 to the Ontario Ministry of the Environment, (1989). In addition, based on the results of leaching studies (described below), where samples of CCA-treated wood of various size were extracted with aqueous solutions at different pH levels over time, the amount of releasable arsenic in the treated wood decreases over time. A conservative estimate of the reduction in the amount of dislodgeable arsenic from freshly treated wood compared to aged wood is approximately 80%, based on the results of leaching studies.

Evans observed about a 20% loss of arsenic in the first few months, from the outer 5 millimeters (mm) of treated poles kept in running water for 10 years, after which no further depletion of arsenic in the wood was detected. See Evans, F.G. "The Leaching of Copper, Chrome and Arsenic from CCA-Impregnated Poles Stored for Ten Years in Running Water," Paper prepared for 10th Annual Meeting of the International Research Group on Wood Preservation, Peebles, Scotland, (1978). In addition, studies that have examined the effect of weathering on the amount of dislodgeable arsenic have found that as the wood ages, the amount of dislodgeable arsenic decreases. See SCS, (1998); Solomon and Warner, (1989). In the SCS study, 5-year old treated wood yielded one-fifth the amount of arsenic compared to fresh wood, when sampled with Kimwipes. In the Solomon and Warner study, wood aged for one year yielded 57-95% less arsenic than when the wood was fresh. Stilwell found that in-place wooden playscapes yielded 78% less dislodgeable arsenic than freshly purchased CCA-treated lumber subjected to only one month of weathering. See Stillwell, D.E. "Environmental Issues on the Use of CCA Treated Wood" (1998) (Attachment 22).

Riedel et al. (1991) also note the decrease in dislodgeable arsenic with weathering. See Riedel, D., J. Harrison, D. Galarneau, D.C. Gregoire, and N. Bertrand "Residues of Arsenic, Chromium and Copper on and Near Outdoor Structures Built of Wood Treated with 'CCA' Type Preservatives" (1991). They discussed an 81% decrease in dislodgeable arsenic in weathered samples compared to fresh samples, but did not state the duration of weathering. The results of these studies are consistent with those reported in a study conducted by the CPSC and the Canadian Wood Preservers Association (CWPA), in which the amount of leachable arsenic dropped quickly over a period of hours to days. See Consumer Products Safety Commission (CPSC) "U.S. Consumer Product Safety Commission Report: Playground Equipment – Transmittal of Estimate of Risk of Skin Cancer from Dislodgeable Arsenic on Pressure Treated Wood Playground Equipment," (1990); Cooper, P.A. "Leaching of CCA from Treated Wood," in Proceedings of the Canadian Wood Preservers Association, Volume II, pp 144-169, (1990). Although they used different protocols, leaching studies conducted by Lebow et al. and Townsend et al. observed a 3- to 10-fold reduction in the amount of arsenic leaching from 20 gram blocks exposed to acidic solutions (pH = 3.0) over a period of three to nine days. See Lebow, S.T., S. A. Halverson, J.J. Morrell, and J. Simonsen "Role of Construction Debris in Release of Copper, Chromium, and Arsenic from Treated Wood Structures" (2000); Townsend, T., K. Stook, T. Tolaymat, J.K. Song, H. Solo-Gabrielle, N. Hosein, and B. Khan "New Lines of CCA-Treated Wood Research: In-Service and Disposal Issues," Report 00-12 (2001). Most of the leaching occurred in the first three days.

The results of these studies indicate that under field conditions, the amount of arsenic released from CCA-treated wood will decrease with age and weathering. Therefore, the assumption in any exposure assessments that the amount of dislodgeable arsenic on the surface of CCA-treated wood remains constant over time will result in an overestimation of exposure to dislodgeable arsenic for most exposure scenarios.

2. Children's Exposure To Arsenic in Soil and Groundcover at Playgrounds with CCA-Treated Wood Playstructures Is Negligible

The other potential exposure route for children at playgrounds with CCA-treated wood equipment is to arsenical compounds that have leached from the wood into the soil. There are two pathways for absorption: dermal and ingestion.

There are numerous factors that must be considered in assessing exposure from soil. The first is the wide variety of ground cover at many playgrounds. Several state agencies mandate, and the CPSC recommends, that playgrounds contain a cover that provides a cushion to prevent injuries from falls. The Public Interest Research Group (PIRG) in connection with the Consumer Federation of America surveyed 1,024 public playgrounds in 27 states and found that 70 percent had some form of soft covering over playground soils. The National Program for Playground Safety funded by the Center for Disease Control and Prevention also conducted two studies which looked at 3,052 playgrounds in all 50 states and found that 78 percent contained adequate surfacing. See Exponent Technical Report. Based on a review of these studies,[16] Exponent concluded that "it is likely that nearly 70 to 80 percent of playgrounds in the U.S. have some form of protective soft covering, thereby potentially eliminating, and certainly reducing, exposures to soils." See Exponent Technical Report.

Other factors that must be considered include soil ingestion rate and the fraction of daily soil ingestion contributed from playgrounds, bioavailability of arsenic from soils, soil exposure frequency and duration, skin surface area exposed to soil contacts, soil to skin adherence factors, and dermal adsorption of arsenic from soil. Exponent concluded that "[w]hile it is important to characterize these exposures as accurately as possible, it is likely that dermal absorption of arsenic from soil contributes a minor component of the total absorbed dose relative to ingestion."

[16] More detailed information about these studies is found in the Exponent Report and Appendix C to that report.

3. Contrary to the Assertions in the Petition, Reliable Data Do Not Indicate that Exposure to Arsenic From CCA-Treated Wood Is More Significant Than Previously Recognized

The petition asserts that exposure to arsenic from CCA-treated wood playground equipment is more significant than previously recognized. The petition also suggests that arsenic exposure can occur via contact with soil at the base of CCA-treated wood playground equipment and other treated wood structures. To support these claims the petitioners identify a series of reports, listed below, that provide information on the potential for human exposure to arsenic from treated wood structures. As identified in the petition, these are: CPSC, (1990); Stillwell, (1998); Galarneau, (1990); Health and Welfare Canada, (1992); California DHS, (1987); Roberts and Ochoa, (2001); Hazardous Substance and Waste Management Research, Inc., (2001). However, as discussed below these reports do not conclusively establish a significant exposure to arsenic from CCA-treated playground equipment.

Exposure data were generated by Stillwell (1997), by Galarneau (1990), by California DHS (1987) and by CPSC (1990). Risk assessments were presented by CPSC, Health and Welfare Canada, California DOHS, Roberts and Ochoa and by Hazardous Substance and Waste Management Research, Inc. Since only two of the risk assessments relied on their own exposure data, variability (and uncertainty) in the exposure data carried over broadly into the risk assessments. For example, measurements of dislodgeable wood surface arsenic vary over four orders of magnitude. This variability manifests in the risk assessments.

A primary reason for this variability appears to be a lack of consistency in methodological approaches employed in these studies. There is no standardized protocol for these types of studies and there is no validated method for sample collection or dislodgeability measurement. Reproducibility of measured values in these studies was often poor. For example, the California DHS study, the study cited by Environmental Working Group/Health Building Network as providing results consistent with all other studies, is based on two subjects wiping a paper tissue (Kimwipe) over the surface of CCA-treated wood or rubbing their hands over a treated wood surface. California Department of Health Services "Report to the Legislature: Evaluation of Hazards Posed by the Use of Wood Preservatives on Playground Equipment," (1987). Direct hand rubbing produced arsenic values ranging from 236 – 1260 μg/hand. It is not clear whether the values represent one hand or two hands. For tissue wipe sampling, one subject provided 6 wipe replicates and the other subject provided 5 replicates. The mean values for dislodgeable arsenic /100cm^2 for each subject were 64.79 and 143.54 μg/100cm^2, a 223% difference between the subjects. For each subject, the replicate values for dislodgeable arsenic ranged from 33.50 – 105.77 and 52.00 – 313.75 μg/100cm^2, respectively. Despite known failures and interferences introduced by fabric wipe testing, the California study did not address the possibility of artifactual findings due to fabric interferences and relied on fabric wipe test results to calculate children's risk from CCA-treated wood playground equipment. The interferences that have been introduced to surface dislodgeability measurements when using fabric wipe techniques include loss of integrity of the wipe (shredding), and interception of whole wood particles by the wipe. The wood particles, which are not residue and are far too large to be considered in hand-to-mouth transfer calculations, have in some instances been subject to chemical analysis for elemental arsenic thereby causing a gross overestimate of the amount of dislodgeable arsenic on the wood surface.

In addition to intra-study and inter-study variability, the level of quality control/data oversight review is not known for any of the studies, and none of the work was conducted or reported in compliance with FIFRA GLP requirements. More importantly, with the possible exception of the 1990 CPSC report, none of the reports provide sufficient detail and description of methodology to permit evaluation of the study findings and an independent interpretation of the study results. For example, one important difficulty in understanding the results of studies reporting soil values of arsenic at treated wood structures, for example, is the question of the soil cover at the site. As documented above, it is common practice in public playgrounds to use sand, wood chip mulch or gravel as ground cover in play areas, particularly at play equipment sites. There is no literature or experience on sampling techniques, chemical analysis (sample desorption) techniques, or most importantly, residue transfer estimation for any of these media. All previous work in the field of environmental exposure assessment is based on soil as the contaminated medium and the medium of transfer to humans. How methods and calculations for contaminated soil uptake and transfer relate to wood chips is not known and is not addressed in the reports if something other than soil as the surface medium was encountered.

- The interpretation of exposure data from CCA-treated wood has been based on inorganic arsenic toxicity, which is, in turn, based on controversial low-dose extrapolations of high-exposure inorganic arsenic ingestion studies.

C. Given Conservative Assumptions, There Are No Unreasonable Risks from CCA-Treated Wood

Gradient Corporation (Gradient) prepared a focused human health risk assessment (HHRA) for Arch Chemicals, Inc., and Osmose, Inc., to quantify potential health risks from exposure to arsenic associated with chromated copper arsenate (CCA) treated wood. [17] The HHRA was conducted in accordance with current United States Environmental Protection Agency (USEPA) risk assessment guidance and recent scientific literature. See U.S. EPA "Risk Assessment Guidance for Superfund (RAGS), Vol. I, Human Health Evaluation Manual (Part A)" (December 1989); U.S. EPA "Dermal Exposure Assessment: Principles and Applications, Interim Report," (January 1992a); U.S. EPA "Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual – Supplemental Guidance: Dermal Risk Assessment Interim Guidance (Final Draft)," (March 1999). The HHRA is focused in that a conservative exposure scenario that included only the pathways likely to be associated with most of the risk were evaluated, rather than a full range of potential exposure scenarios and pathways. In addition, it was assumed that hand loading of "dislodgeable arsenic"[18] does not decrease with the age of the

[17] The HHRA has been submitted to the Commission. In addition, the full report may be found on the web at http://www.preservedwood.com/safety/research_ccafocus.html.

[18] It should be noted that arsenic in the dislodgeable form is present as chromium arsenate (Bull, (2000), (2001); Cooper, P.A., D.L. Alexander, and T. Ung "What is Chemical Fixation" in Chromium-Containing Waterborne Wood Preservatives: Fixation and Environmental Issues (J. Winandy and M. Barnes, Eds.), Forest Products Society (1993); Kamdem, (2001) and is only a small fraction of the dislodgeable material on treated wood. See Cui, W. "Surface Arsenic (Continued ...)

deck, the concentration of arsenic in soil located beneath the residential deck is the same as in soil located near a play structure, and that all of the time outdoors is spent exposed to treated wood and impacted soil. These assumptions are likely to result in an overestimate of exposure, and consequently risk, as discussed above.

Two exposure pathways were evaluated in the HHRA: exposure to arsenic on the surface of CCA-treated wood (eight treated wood types were evaluated) and exposure to arsenic in soil located below a CCA-treated wooden deck at a residence. The eight wood types consisted of six samples of wood treated with Osmose chemicals purchased at retail, and two samples aged at the Osmose Research Division. These wood samples reflected readily available factory-treated CCA wood.

Cancer and non-cancer health risks were assessed for a residential exposure scenario, which included a male/female child ages 2-6 years, and a male/female child and adult ages 7-31 years. The residential receptors were assumed to be exposed *via* incidental ingestion to dislodgeable arsenic, which is arsenic on the surface of CCA-treated wood that can be removed from the wood surface by dermal contact with the hands. The other exposure pathways evaluated in the HHRA for the residential receptors included incidental ingestion and dermal contact with arsenic in soil located below a CCA-treated deck. It was assumed that most of the arsenic in these soils is the result of metal that has migrated (*via* rainwater run-off) from the treated wood to the soil below. Consistent with USEPA risk assessment guidance, reasonable maximum exposure (RME) parameters were used to assess health risks for the subchronic and chronic exposure scenarios (USEPA, 1989). Thus, the calculated risks would be overestimates for the average child. Subchronic risks were calculated for the child resident ages 2-6 years. Chronic risks for the child and adult resident, ages 2-31 years, were estimated by combining the doses for the 2-6 year old and 7-31 year old receptors, and basing risks on a time-adjusted chronic dose.

Analysis of Commercial CCA Treated Southern Pine," (2001); Osmose, "Surface Chemical Analysis of CCA Treated Southern Pine Lumber," Research Document 33-258 (2001).

The estimated cancer and non-cancer health risks for the subchronic and chronic exposure scenarios are summarized in Tables 1 and 2 below.

Table 1
Summary of Estimated Cancer Risks

Exposure Medium	Resident Receptor	
	Ages 2-6	Ages 2-31
Soil Arsenic (includes ingestion and dermal exposure)	8.0E-07	1.1E-06
Dislodgeable Arsenic from Southern Pine (1)	3.5E-06	6.0E-06
Dislodgeable Arsenic from Southern Pine w/ Pressure-Applied Water Repellent (2)	7.4E-06	1.3E-05

(1) This wood type was included because it accounts for approximately 86% of the treated lumber and timber used in the U.S. American Wood Preservers' Association (AWPA) report prepared by James T. Micklewright, Consulting Forest Products Technologist (1998).
(2) This wood type was included because it resulted in the highest risk from exposure to dislodgeable arsenic. It should be noted that this wood type accounts for only about 6% of the treated lumber sold in the U.S. Research Information Systems, Inc. (RISI), *"Treated Wood – the Markets for Treated Lumber, Timbers and Plywood, Volume II"* (1990).

Table 2
Summary of Estimated Non-Cancer Risks

Exposure Medium	Resident Receptor	
	Ages 2-6	Ages 2-31
Soil Arsenic (includes ingestion and dermal exposure)	1.2E-03	5.5E-03
Dislodgeable Arsenic from Southern Pine (1)	5.4E-03	3.1E-02
Dislodgeable Arsenic from Southern Pine w/ Pressure-Applied Water Repellent (2)	1.2E-02	6.6E-02

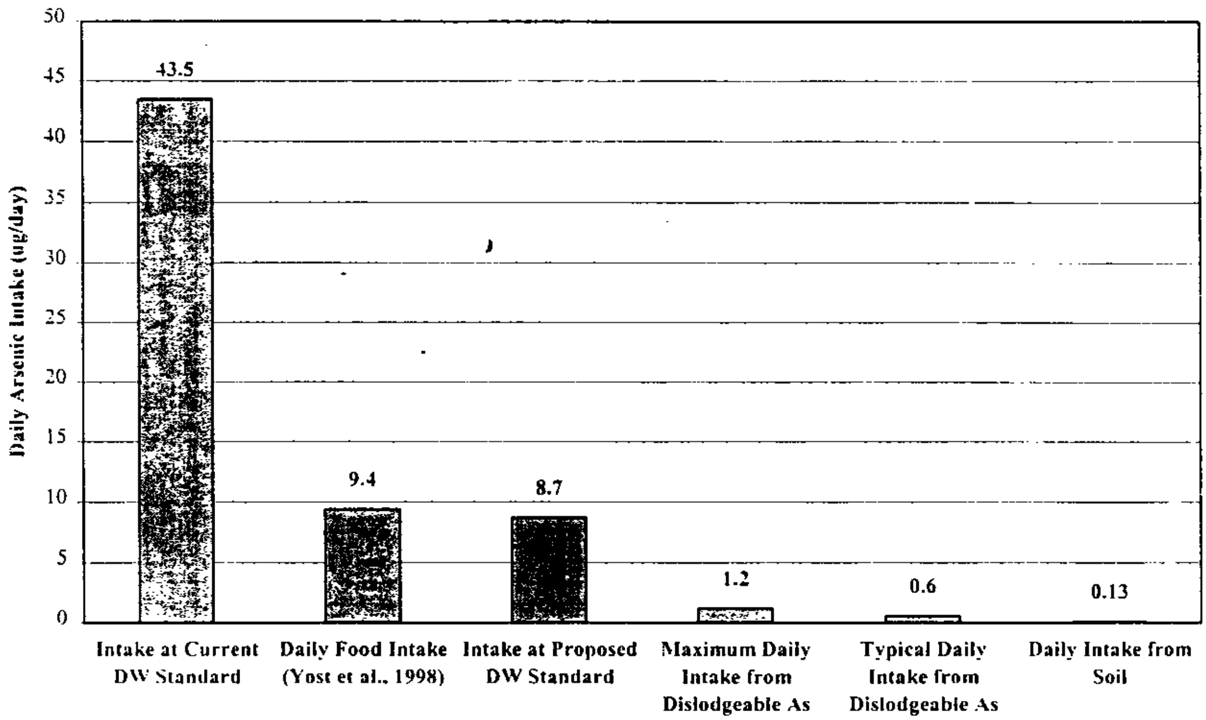
(1) This wood type was included because it accounts for approximately 86% of the treated lumber and timber used in the U.S. AWPA, (1998).
(2) This wood type was included because it resulted in the highest risk from exposure to dislodgeable arsenic. It should be noted that this wood type accounts for only about 6% of the treated lumber sold in the U.S. RISI, (1990).

Based on the results of the HHRA, the estimated cancer and non-cancer risks do not exceed EPA's acceptable risk limits of 1E-06 to 1E-04 for cancer and 1.0 for non-cancer. This range of acceptable risk limits is consistent with values used by other regulatory agencies. Because these risk estimates are based on RME parameters and contain a number of conservative assumptions, they are likely an overestimate of actual risks. For example, the exposure frequency used for both the subchronic and chronic exposure scenarios was based on the amount of time spent outdoors at any location, rather than time spent outdoors at a residence. This parameter overestimates exposure frequency and risk by over two-fold for more typical subchronic exposures. As another example, the HHRA did not address the approximately five-fold reduction in the amount of dislodgeable arsenic that occurs with time. Consideration of the reduction in the amount of dislodegable arsenic would reduce chronic risks several-fold.

It is also important to recognize that the contribution of arsenic from CCA-treated wood to a child or an adult's daily exposure to arsenic would be modest. As can be seen in Figures 1 and 2 (below and following page), the amount of arsenic from CCA-treated wood is well below what an individual receives from food and would not have a discernable impact on exposure.

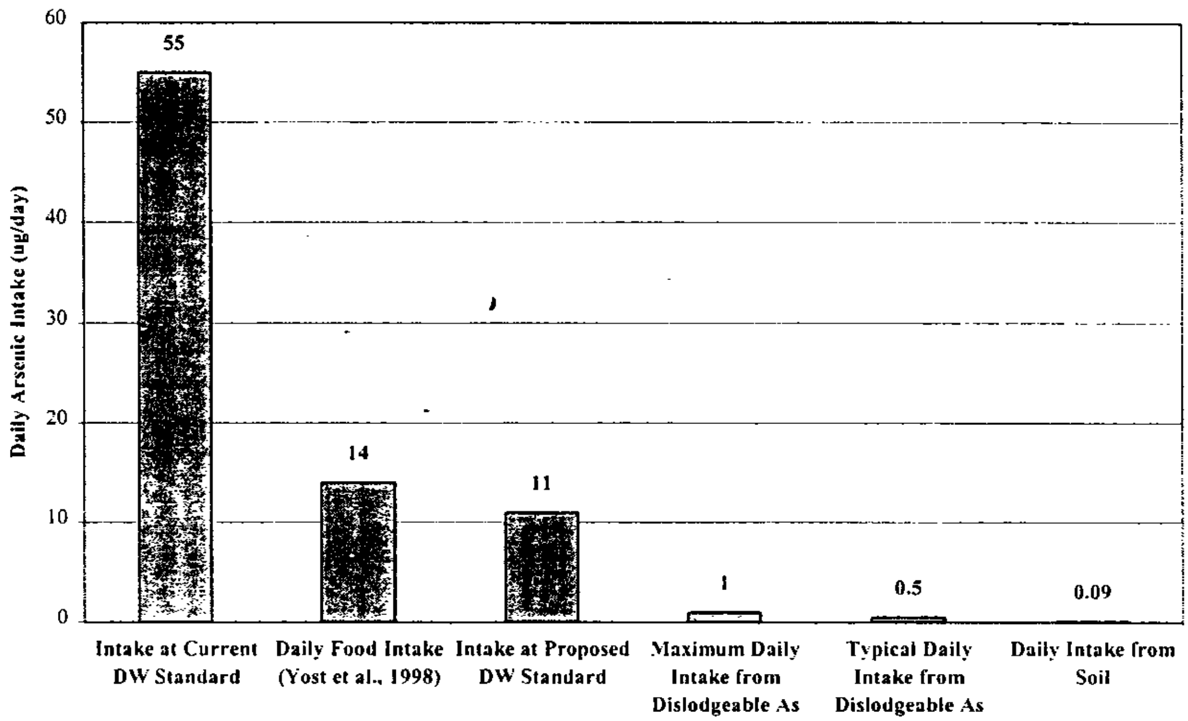
The low contribution of inorganic arsenic from CCA-treated wood, compared to other sources, has a negligible effect on total daily exposure, which should be a consideration to risk managers.

Figure 1
Comparison of Inorganic Arsenic Doses for Subchronic (Ages 2-6) Exposures



Notes:
1) Arsenic intakes from drinking water are based on the current (50 µg/L) and proposed (10 µg/L) federal drinking water standards for arsenic, and were calculated using USEPA-recommended mean drinking water intake rates for children ages 3-5 (0.87 L/day); and a time-weighted average of drinking water intake rates for a child and adult receptor ages 2-31 years (1.1 L/day). USEPA, (1997).
2) Dietary intake of inorganic arsenic for the subchronic receptor (ages 2-6) is based on a child ages 6 months – 2 years. This intake rate will likely underestimate the daily dietary intake of inorganic As used for the subchronic receptor.
3) The maximum dislodgeable arsenic intake is based on the wood type (*i.e.*, CCA-Southern Pine with pressure-applied water repellent) resulting in the highest daily dose of arsenic from incidental ingestion.
4) The typical dislodgeable arsenic intake is based on the wood type (*i.e.*, CCA-treated Southern Pine) most commonly used in the U.S. AWPA, (1998).
5) Soil arsenic intake is based on ingestion and dermal exposure to arsenic in soil.

Figure 2
Comparison of Inorganic Arsenic Doses for Chronic (Ages 2-31) Exposures



Notes:
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2) Dietary intake of inorganic arsenic for the subchronic receptor (ages 2-6) is based on a child ages 6 months – 2 years. This intake rate will likely underestimate the daily dietary intake of inorganic As used for the subchronic receptor.
3) The maximum dislodgeable arsenic intake is based on the wood type (*i.e.*, CCA-Southern Pine with pressure-applied water repellent) resulting in the highest daily dose of arsenic from incidental ingestion.
4) The typical dislodgeable arsenic intake is based on the wood type (*i.e.*, CCA-treated Southern Pine) most commonly used in the U.S. AWPA, (1998).
5) Soil arsenic intake is based on ingestion and dermal exposure to arsenic in soil.

CONCLUSION

The Commenting Trade Associations submit that CPSC should deny Petition HP 01-3 and take no further regulatory action on CCA-treated wood. Pursuant to 16 C.F.R. § 1051.6, the CPSC should not consider Petition HP 01-3 to be a proper "petition" as it "involves a product outside the jurisdiction of the Commission." EPA already regulates CCA-treated wood and its end uses as pesticides under FIFRA, and the FHSA and the CPSC dictate that such pesticides are not subject to CPSC's jurisdiction. Furthermore, the Commission should deny the petition because CCA-treated wood does not present an unreasonable health risk and no CPSC rulemaking is necessary to prevent harm, especially considering EPA's regulation of the same product. See 16 C.F.R. § 1051.9. EPA's extensive regulation of CCA, CCA-treated wood, and its end uses makes additional regulation by the CPSC unnecessary, duplicative, and confusing.

Existing studies demonstrate that the use of CCA-treated wood in playground equipment does not pose an unreasonable risk to children; therefore, additional regulation of this product is unnecessary.

Stevenson, Todd A.

From: Watson, Sara Beth [SWatson@steptoe.com]
Sent: Tuesday, September 11, 2001 1:34 PM
To: 'cpsc-os@cpsc.gov'
Cc: Has Shah (E-mail); 'pbittner@cpsc.gov'
Subject: Petition HP 01-3, Petition for Ban on Use of CCA Treated Wood in Playground Equipment

ltrcpsc.doc   cpsccomments.doc

Attached are the cover letter and comments on "Petition HP 01-3, Petition for Ban on Use of CCA Treated Wood in Playground Equipment" from the American Chemistry Council Biocides Panel Arsenical Wood Preservatives Task Force and the American Wood Preservers Institute. Due to the terrorist attacks today, we are unable to file the attachments. We will file with your office five hard copies of the comments and all attachments as soon as possible.

<<ltrcpsc.doc>> <<cpsccomments.doc>>

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September 11, 2001

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

Via E:Mail: cpsc-os@cpsc.gov

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

Ladies and Gentlemen:

The American Forest & Paper Association ("AF&PA") appreciates the opportunity to comment on the petition from the Environmental Working Group and the Healthy Building Network (hereinafter "Petitioners") seeking a ban of wood treated with CCA for use in playground equipment.

AF&PA members use CCA or supply lumber for treatment, but do not manufacture CCA. AF&PA's interest is in ensuring the Petition is carefully evaluated using good science and appropriate legal standards. We would be pleased to engage in further dialog with the Commission or to supply additional input if that would be helpful in the Commission's deliberations. We note below some issues that appear readily from the face of the Petition. We urge the Commission to scrutinize the Petition carefully.

Legal Background

First, although the petition invokes both the Consumer Product Safety Act and the Federal Hazardous Substances Act ("FHSA"), we note that the Commission has appropriately docketed the petition under the FHSA. As the court noted in *Gulf South Insulation v. U.S. Consumer Product Safety Commission*, 701 F.2d 1137, 1149 (5th Cir. 1983), in setting aside a product ban based on alleged carcinogenicity, there are "important procedural rights guaranteed by the Federal Hazardous Substances Act." Among these protections are the use of a Chronic Hazard Advisory Panel pursuant to 15 U.S.C. §§ 2077, 2080, and a formal hearing and findings based on substantial evidence to address whether the substance is hazardous, under 15 U.S.C. § 1262(a). While the hearing applies only when necessary to resolve uncertainty as to the application of the statutory provisions, such ambiguity would most assuredly be present here were the Commission to decide to act on the Petition. We do not believe the Petition presents a sufficient case to justify such a classification of CCA-treated playground equipment as a hazardous substance,[1] much less to adopt a ban under the FHSA.

A decision to move forward would entail a substantial commitment of Commission resources.[2] In publishing a ban or other regulation under 15 U.S.C. §§ 1261, 1262, CPSC must find that a voluntary standard would not adequately reduce risk, that the benefits of the regulation bear a reasonable relationship to its cost, and that the regulation imposes the least burdensome requirement that prevents or adequately reduces the risk of injury. Petitioners have not addressed any of these elements. The only acknowledgement in the Petition of these issues is when Petitioners assert (at page 7) that a product safety standard is not adequate because there is a risk from playground equipment -- a conclusion which does not follow.

The Petition contains a number of statements that do not withstand close scrutiny. We highlight several examples below.

Carcinogenic Potency of Arsenic

Petitioners broadly assert that a 1999 National Research Council (NRC 1999) "study" concluded that "arsenic is a much more potent carcinogen than previously recognized." While we are familiar with the National Research Council's report reviewing the literature, nowhere in the report can we find such a conclusion.[3] We recognize, however, that the update of the NRC Report to be released this week (NRC 2001) may require further evaluation.

---

[1] To classify CCA-treated playground equipment as hazardous, CPSC would have to conclude the product causes "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." 15 U.S. C. § 1261(f)(1)(a).

[2] In evaluating the Petition, CPSC must evaluate several factors, including whether the product presents an unreasonable risk of injury and whether a rule is reasonably necessary to eliminate or reduce the risk of injury. 16 C.F.R. 1951.9(a).

[3] The 1999 NRC report states that "the subcommittee believes that the evidence is now sufficient to include bladder and lung cancer among the cancers that can be caused by ingestion of inorganic arsenic." (NRC at p. 130) However, the two sentences immediately following that conclusion in the report observe: "With minor exception, the epidemiological evidence for cancer comes from places where exposed populations were exposed to arsenic concentration in drinking water of at least several hundred micrograms per liter. Few data address the degree of cancer risk at lower concentrations of ingested arsenic." Id. Moreover, the 1999 NRC "subcommittee has not tried to perform a definitive risk assessment." Id. at 295. The subcommittee used bladder cancer data "to illustrate statistical issues that arise in this context," id. at 296, but did not provide a full quantitative risk assessment.

While we understand from a very brief review of a pre-publication copy that the new NRC 2001 report does address dose-response assessment, we note that the focus of that report is on *ingestion of drinking water. Even in that context, the updated report notes the need for* "improved characterization of the form and bioavailability of the arsenic present in the raw foods and of the arsenic incorporated into food from drinking water during cooking and food preparation." Arsenic in Drinking Water: 2001 Update (Sept. 2001, pre-publication copy) (NRC 2001), at page 134.

Bioavailability in the context of exposure to treated wood is even more complex, and must be considered before applying data or calculations for cancer or any other endpoint based on ingestion of drinking water. CPSC's guidelines strongly emphasize the importance of bioavailability in exposure assessment:

> [T]he manufacturer must account for the amount of the substance in the product, for the bioavailability of the substance, and for exposure to the substance. (57 *Fed. Reg.* at 46631.)
>
> . . .
>
> [B]ioavailability, which is concerned with the ability of a substance to be absorbed into the body, is one part of the inquiry into whether a toxic substance is "hazardous" under the FHSA. (57 *Fed. Reg.* at 46648.)
>
> . . .
>
> Bioavailability should be considered during the exposure/risk assessment of a toxic substance if there is reason to believe that the dosing conditions used in the dose-response study would introduce a non-linearity in absorption when extrapolating to conditions encountered during human exposure. Animal toxicity and human epidemiology studies on which risk assessment is based often involve chemical exposures that are higher than exposures resulting from use of consumer products. Risk assessments usually predict toxicity at those lower doses using mathematical models that do not fully apply the biological non-linearities that can sometimes exist. (Id.)

One factor CPSC emphasizes with respect to bioavailability is particularly relevant here: the physical or chemical form of the substance at issue.

> If the physical or chemical form of a toxic substance in a product differs from the form present in the dose-response studies used to assess risk, the comparative bioavailability of the forms of the substance must be evaluated. This is particularly true of the toxic

> metals which can exist as water soluble salts, water insoluble salts, alkyl compounds, and in various states of polymeric aggregation. All of these forms differ in their ability to be absorbed across biological surfaces. (Id.)

Recent data, cited in Gradient's "Focused Evaluation of Human Health Risks Associated with Exposure to Arsenic from CCA-Treated Wood," (July 6, 2001, prepared for Arch Chemicals, Inc. and Osmose), indicate the predominant species of arsenic in CCA-treated wood is chromium arsenate. The implications of this compound and the arsenic valence state for potential bioavailability and methylation need to be considered. It is well established that arsenic in the +5 valence state is less mobile and soluble than +3 arsenite. These issues may require adjustments in the risk assessment for bioavailability.

As the new NRC 2001 report acknowledges, many uncertainties remain in the risk assessment for arsenic even in drinking water. For example, the mechanism of arsenic's potential carcinogenic action, particularly at low doses, is unknown. The quantitative calculations in the NRC 2001 report rely on a benchmark dose approach, with linear extrapolation below the ED_{01}. Both the choice of the ED_{01} rather than the ED_{10} and the decision to use linear extrapolation below that level are, at least in part, policy decisions. NRC 2001, at 9, 181.

Non-Cancer Effects

We are concerned by similarly overreaching statements in the Petition regarding purported noncancer effects. Petitioners rely on "[r]esearch by NRC and others since 1990 which has also shown arsenic to be an endocrine disruptor, and has linked arsenic ingestion to immune system suppression, increased risks of high blood pressure, cardiovascular disease, and diabetes." (Petition at 1.) Comparing each of Petitioners' allegations with the NRC 1999 report they cite is revealing:

- Petitioners cite a single study published subsequent to the 1999 NRC Report for the proposition that arsenic "acts as an endocrine disruptor at low concentrations: between 25 and 50 micrograms per liter (Kaltreider 2001)." (Petition at 3.) This study is an *in vitro* (test tube) study of the biochemical function of the glucocorticoid receptor done in hormone-responsive rat hepatoma cells – representing neither humans nor even whole animals. We hardly need point out the uncertainties associated with such measures of endocrine disruption, or the perils of relying on a single, unreplicated study.

- As for immune system suppression, NRC 1999 notes that inorganic arsenic has been shown to have immunomodulating and immunotoxic effects in experimental models. With respect to human data, NRC cites a 1982 "pilot" study from Michigan "consistent with an immunomodulating effect;" that single unpublished study reported increased incidence of herpes-related cold sores and shingles in a very small number of subjects exposed at relatively high concentrations of arsenic in drinking water. However, NRC concluded "[t]he potential effect of exposure to low concentrations of arsenic on immune function has not been adequately investigated in field research . . . ." NRC 1999 at 132.

- Regarding diabetes, NRC 1999 states: "Recent studies in southwestern Taiwan and Bangladesh associated chronic arsenic ingestion in drinking water with an increased risk of diabetes mellitus. The study subjects were drawn from populations with overt cutaneous signs of arsenic intoxication; information is lacking on the magnitude of the potential risk associated with exposure to low concentrations of arsenic." NRC 1999 at 132. The circumstances addressed in the Petition are quite different. There is no allegation that children on playgrounds are suffering overt cutaneous signs of arsenic intoxication. (NRC 2001 cites recent data from two ecological studies in Taiwan in which median drinking water concentrations were 700-900 ug/l, and recommends qualitative consideration of these data since "the magnitude of possible risk that exists at low levels is not quantifiable." NRC 2001 at 3, 31.)

- With regard to cardiovascular disease, NRC 1999 notes that recent findings in Taiwan associated a risk of hypertension and cardiovascular mortality with cumulative arsenic ingestion. However, "[a]lthough investigators estimated individual arsenic doses in several studies, the reports do not reveal the extent of the cardiovascular risk, in the absence of cutaneous effects, from exposure to low concentrations of arsenic." NRC 1999 at 132. Thus, applicability of these findings to the exposure conditions addressed by the Petition is questionable. (Again NRC 2001 recommends qualitative consideration of these data since "the magnitude of possible risk that exists at low levels is not quantifiable." NRC 2001 at 3, 31.)

Exposure Conditions

Exposure assessment requires consideration of a number of factors. While Petitioners describe some of the universe of exposure data, a critical review of exposure would be necessary.[4] For instance, the study by the California Department of Health Services that Petitioners cite of volunteers who rubbed municipal playground equipment was based on a sample of five persons. Petitioners omit mention of several additional studies such as those by the Maine Department of Human Services, Scientific Certification Systems (a particularly detailed study of eight types of wood and a control of untreated wood), and others. No single one of these studies is perfect, although the weight of the evidence as a whole is instructive. As the Commission has observed, "defining a reasonable use scenario can be the most uncertain part of exposure assessment. As

[4] Petitioners also cite data regarding intake of arsenic from food and water, but as with the exposure information, they do not explore the full range of available data on this topic.

the guidelines indicate, there are many variables to consider." 57 Fed. Reg. 46626, 46631 (Oct. 9, 1992).[5]

An expert report prepared by Exponent for the Arsenical Wood Preservatives Task Force for submission to EPA recently reviewed the "Technical Issues Associated with the Risk Assessment of Children's Exposure to Arsenic at Playgrounds with Structures Constructed from CCA-Treated Wood" (July 31, 2001). Exponent examined key exposure pathways, and reviewed substantial amounts of exposure information. Among the many parameters, ones for which additional data may aid in improving the risk assessments include:

> For Soil Ingestion Pathway: chemical concentration in soil, fraction ingested, exposure frequency, relative oral bioavailability
>
> For Dermal Contact with Soil: chemical concentration in soil, dermal absorption factor, exposure frequency
>
> For Ingestion of Dislodgeable Arsenic: chemical concentration on wood, transfer efficiency wood to skin, hand-to-mouth activity, exposure frequency, relative bioavailability from wood residue
>
> For Dermal Contact with Wood: chemical concentration on wood, surface area of palms and soles, transfer efficiency wood to skin, dermal absorption factor, exposure frequency

Petitioners rely heavily on a letter from University of Florida researchers, who noted the variability in exposure assumptions across several different risk assessments for CCA-treated wood. For instance, the letter states: "The enormous variability in results makes it difficult to select a single concentration of dislodgeable arsenic as being representative of playground surfaces or decks." Roberts and Ochoa, April 10, 2001, at 2. For their own assessment, the University of Florida researchers assume daily exposure for five years, while noting this is "highly conservative in the sense that it is extremely unlikely that an individual will have contact with CCA-treated wood every single day." Roberts and Ochoa, April 10, 2001, at 6. The Roberts and Ochoa assessment also assumes 100% bioavailability.

CPSC, however, generally does not base its assessments on worst case conditions:

> In most cases the best estimate of exposure (average exposure) is acceptable. Conservative estimates (i.e., those which may lead to overestimates of exposure, such as the upper confidence limit, "reasonable worst case," or "maximum exposed individual") are not required, but may be more appropriate in some cases.

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[5] Our citation of CPSC's 1992 non-binding guidelines for evaluating guidelines for evaluating chronic toxicity does not imply complete agreement with the approach described there, but the guidelines provide a useful starting point.

CPSC, preamble to Guidelines for Determining Chronic Toxicity of Products Subject to the FHSA, 57 Fed. Reg. 46626, 46647 (October 9, 1992). Many of the calculated risk predictions presented in the Petition, however, rely on such upper bound or worst case approaches. [6]

In short, extensive data are available and need to be reviewed, but many issues are presented with respect to exposure assessment.

Complaint Data

We take strong exception to the Petition's reliance (Petition at 5) on data from complaints and personal injury litigation settlements. Settlements of tort litigation in no way establish a causal connection between the alleged exposure and an alleged injury. Even case reports published in peer-reviewed medical literature are generally used only for hypothesis generation. The Petitioners' assertions with regard to alleged cases of "arsenic poisoning" -- none of them related to playground equipment -- are inadequate to support any findings or action by the Commission.

Conclusion

AF&PA's interest is in ensuring that the Petition is carefully evaluated using good science and appropriate legal standards. While we appreciate the Petitioners' concerns, extensive review of CCA is already underway at EPA, including review of risk assessments by external peer reviewers. Further scientific research is also underway, and AF&PA and its members hope to contribute to the vast body of available literature. The public interest can best be served by rigorous scientific review and by coordination of these various efforts.

Should you have any questions or wish to discuss these comments, please do not hesitate to contact me at 202-463-2587.

Respectfully submitted,

John L. Festa, Ph.D.
Senior Scientist

---

6 Compare *Gulf South Insulation, supra,* finding that "up to" numbers [upper confidence limits] do not constitute substantial evidence.

Stevenson, Todd A.

From: martina_feenster@afandpa.org
Sent: Wednesday, September 12, 2001 2:29 PM
To: Cpsc-os@cpsc.gov
Cc: john_festa@afandpa.org
Subject: Petition HP-01-3

cpsc.doc

We have enclosed for filing our comments on petition HP-01-3.

Martinã D. Feenster
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CCA petition

Ann Brown, Chairperson
U.S. Consumer Products Safety Commission
Washington, DC 20207-0001

Dear Chairperson Brown:

Please immediately ban arsenic in children's playground equipment, and review the use of arsenic in all outdoor treated wood products.

Just by playing on an arsenic-treated playground for 10 days, a five-year-old gets exposed to more arsenic than she should in a lifetime. Arsenic can cause skin, bladder and lung cancer, and is linked to diabetes and endocrine disruption.

Safer alternatives exist to treat outdoor wooden structures. No child should be poisoned by playing.

Sincerely,

Jeff Hobson
2720 Sacramento St
Berkeley CA 94702