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December 13, 2006

Stephen Johnson
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re. Registration of Acid Copper Chromate (ACC); Petition to Cancel Uses

Dear Mr. Johnson:

Please consider this submission both a petition for cancellation of Acid Copper Chromate (ACC) and formal comments to be considered as a part of the agency's current deliberations on expanding ACC to residential uses. The undersigned organizations are writing to express serious concerns about EPA continuing to move forward with the allowance of ACC treatment of wood for residential uses, expanding on its earlier decision to allow commercial uses in July, 2006.

To add to the overwhelming body of evidence that supports prohibiting both the purposeful and unintended (as toxic waste) introduction of hexavalent chromium into the environment, we are attaching a background paper, *Acid Copper Chromate: No need for a carcinogenic wood preservative approved on SHAKY Science*, which provides the scientific support for our position to ensure that all uses of ACC are prohibited.

We urge EPA to seriously reconsider and reverse the track it is on and prohibit any continued use to protect public health and the environment.

Sincerely,

Jay Feldman, Beyond Pesticides
Bill Walsh, Healthy Building Network
Jennifer Sass, Ph.D., Natural Resources Defense Council
Monica Moore, Pesticide Action Network North America
Steve Breyman, Citizens' Environmental Coalition
Paul Schwartz, Clean Water Action
Diana McKeown, Clean Water Action Midwest Office
Kathleen Burns, Ph.D., Sciencecorps
Michael R. Harbut, MD, MPH, FCCP

CC. Marcus Peacock
Susan Hazen
Frank Sanders
Jack Housenger
Tim Leighton
James Gulliford
James Jones
Mark Hartman
Timothy McMahon

ACID COPPER CHROMATE:

NO NEED FOR A CARCINOGENIC WOOD PRESERVATIVE APPROVED ON SHAKY SCIENCE

Background Briefing Paper

December 2006

Executive Summary

In 2002, the U.S. Environmental Protection Agency (EPA) cooperated with the chemical industry to end the use of arsenic- and chromium-treated woods for residential consumer use. However, in May 2006, the U.S. Environmental Protection Agency (EPA) granted the Forest Products Research Laboratory[1] restricted use registration for ACC (acid copper chromate), a hexavalent chromium-based wood preservative. EPA's decision allows ACC to be used for certain commercial wood products but precludes its use for most residential purposes. Hexavalent chromium is a known carcinogen. *FPRL, however, has applied for an unrestricted registration that would allow the company to sell ACC for use in all exterior wood products – including those used for residential, school and playground use.*

This report provides:

- A summary of the consequences resulting from an EPA decision to grant FPRL an unrestricted registration for ACC.

- An analysis of the studies (including FPRL-sponsored reports) that are being used by EPA's Office of Pesticide Programs to make its decision on ACC.

The environmental and public health stakes are high. The consequences of an across-the-board approval for ACC are likely to be significant. ACC is being promoted as a low-cost alternative to a number of safer, arsenic and chromium-free products that are already commercially available. With its high hexavalent chromium content (it contains about one-and-a-half times more Cr^{+6} than CCA[2]), its approval and widespread use will reintroduce tens of millions of pounds hexavalent chromium into workplaces and consumer products each year[3] and will pose numerous risks to those exposed.

The evidence contained in EPA risk assessments, published studies and even FPRL's own reports demonstrate a number of unacceptably high risks to those who would produce, work

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[1] The Forest Products Research Laboratory is a private company and is not affiliated with the Forest Products Laboratory of the U.S. Forest Service (USDA).

[2] CCA stands for chromated copper arsenate, a product that contains both hexavalent chromium and arsenic.

[3] The Forest Products Research Laboratory reports that, if EPA approves the unrestricted ACC application, the industry will demand 40,000 metric tons of chromic acid (hexavalent chromium) annually.

with, and use ACC pressure treated wood if EPA approves wider use. These risks include:

- **Cancer Risks for Plant Workers:** Many workers in ACC-wood treatment plants would experience cancer risks greater than EPA's acceptable range due to their inhalation of hexavalent chromium.

- **Cancer Risks for Woodworkers:** Workers who operate woodworking equipment (e.g. sawing and sanding machines) would also experience cancer risks that exceed EPA's acceptable levels. EPA has found that, even in OSHA compliant workplaces, that workers exposed to dust from ACC-treated southern pine would experience cancer risks in the range of approximately 10^{-4} to 10^{-3} (1 per 10,000 to 1 per 1000) these levels are above EPA's highest acceptable cancer risk. EPA has not assessed cancer risks in workplaces that are non-compliant with OSHA safeguards.

- **Skin Reactions:** Hexavalent chromium represents the second most common skin allergen in humans.[4] Effects can include blemished skin, rashes, redness, itching, and severe discomfort, as well as emotional distress and loss of work. While the symptoms may be reversible, the underlying sensitization remains; additional exposures cause repeated bouts of symptoms.

    - Residues of hexavalent chromium on ACC-treated wood exceed levels likely to cause outbreaks of allergic skin disease in those exposed to treatment solutions (e.g. treatment plant workers), those who work with wood (such as carpenters) and those who are exposed to products such as outdoor decks, fences, tables and playground equipment.

    - EPA's risk assessment presents evidence that the hexavalent chromium in ACC-treated wood does not convert immediately to less toxic trivalent chromium. Thus, residues of hexavalent chromium can remain on the surface of the product or drip from the product for weeks and months following treatment. Unconverted hexavalent copper can also remain in interior wood for extended periods.

    - The rates of hexavalent chromium are highly variable based on the type of wood, the climate, and other factors and EPA has found it difficult to reliably predict the rate at which hexavalent chromium decreases. Additional studies will be needed in order for EPA to ensure that workers and consumers who handle ACC-treated wood are taken into account since dermal exposure can both sensitize people to hexavalent chromium and trigger allergic reactions.

- **Risk of Future Superfund and Brownfield Sites:** Many Superfund and brownfield sites have already been created at former plants that produced and used hexavalent chromium for wood treatment. Soil and groundwater contamination from chromium will be a greater risk if widespread production is permitted through EPA's approval.

- **Huge Amounts of Long-Term Discarded Wood Waste:** With a typical life of 10 years, tens of millions of cubic feet of chromium-treated wood will be discarded as waste across America, threatening soil and groundwater and straining state enforcement authorities.

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[4] Haines, A. T. and Nieboer, E.: 1988; "Chromium hypersensitivity." Adv. Environ. Science and Technology, Vol. 20, pp. 497-532.

Dermal exposure science remains shaky. EPA has acknowledged the wide range of potential risks from hexavalent chromium wood treatment chemicals, including cancer risks from inhalation, occupational exposure, contaminated sites, and discarded wood waste. However, EPA appears to be focusing its current review on a narrow assessment of only dermal exposure risks. Yet, even this narrow focus on dermal exposure raises substantial concerns about shaky, incomplete science propelled by the applicant without any public or peer review.

This report discusses two studies that EPA is currently using to set an allowable dermal exposure level for hexavalent chromium (the Nethercott study[5] and the ROAT study[6]). Both studies show a minimal elicitation level (10%) of approximately 0.09ug Cr^{+6}/cm^2. Using the standard default uncertainty factor led EPA in 2004 to establish an interim allowable dermal exposure level of $0.009ug/cm^2$. EPA is currently determining whether to retain this level, or modify this level in a manner that may allow widespread residential use of ACC-treated wood products.

A study prepared by Osmose shows that the highly toxic hexavalent chromium persists in ACC-treated wood residues at levels which exceed the 0.009 allowable dermal exposure level for periods lasting for weeks to months.[7] An EPA review of the study states, *"Do not suggest that holding time can adequately predict the level of dislodgeable Cr^{+6} on the surface of wood that has been treated with ACC. The internal levels of Cr^{+6} are reported to be highly variable, even among individual boards treated at the same time in one unit. This high variability does not allow for an estimation of the rate of reduction."* [8] Thus EPA must presume that those in contact with ACC-treated wood even after extended periods will be exposed to unconverted hexavalent chromium at levels capable of causing an allergic response in chromium-sensitive individuals.

In summary, EPA does not have adequate data to ensure that the public and especially persons who are sensitized to chromium will be protected if the Agency allows the unrestricted use of ACC. In fact, as presented in this report, the evidence available indicates that widespread use of this preservative will cause unhealthful dermal exposures of workers and consumers to hexavalent chromium. Secondly, EPA should not accept a limited assessment consisting of dermal exposure alone, to the exclusion of all other risks and especially those related to cancer.

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[5] Nethercott, J, et al., "A study of chromium induced allergic contact dermatitis with 54 volunteers: implications for environmental risk assessment, John Hopkins University, *Occupational and Environmental Medicine,* Vol. 51, 371-380, 1994.

[6] This study is not readily accessible to the public. However, a fairly detailed summary of the ROAT study is on an EPA website. McMahon, Tim; Antimicrobials Division: OPP / EPA, Data Evaluation Record, Skin Sensitization non-guideline (Repeat Open Application Test).

[7] Leighton, Tim, Antimicrobials Division, OPP / EPA, Memorandum to Mark Hartman, *Review of the "Osmose ACC 50% Wood Preservative: Determination of Hexavalent Chromium Residues In and On Wood Following Treatment with Acid Copper Chromate,* May 30, 2006.

[8] Leighton, Tim, U.S. EPA, OPP, Antimicrobials Division, Memorandum, "Review of the "Osmose ACC 50% Wood Preservative: Determination of Hexavalent Chromium Residuals In and On Wood Following Treatment with Acid Copper Chromate." May 30, 2006.

Recommendations. EPA has the power to deny the registration of ACC and for the reasons discussed above should:

- Retain its current regulatory level for dermal exposure or designate a lower and more protective standard.
- Deny FPRL's application for unlimited use and prevent ACC-treated wood from being used in home, school and playground applications.
- Rescind the restricted registration for ACC granted in May of this year.

1.0 Introduction

1.1 Background. In 2003, the wood preservative industry working in cooperation with the U.S. Environmental Protection Agency (EPA) agreed to phaseout the use of CCA-treated wood for residential purposes. CCA, chromated copper arsenate, the dominant wood preservative for many decades, contains two carcinogenic metals, arsenic and hexavalent chromium. The voluntary phase-out was a response to widespread concerns that children and others would be harmed by their exposure to arsenic and chromium residues contained on the surfaces of decks, picnic tables, playground equipment and other outdoor wooden structures. To accomplish the phaseout, the nation's major preservative manufacturers invested tens of millions of dollars in alternatives that contain neither arsenic nor hexavalent chromium (Cr^{+6}). These safer alternatives are now fully available and used across the United States. Since 2003, this investment has kept hundreds of millions of pounds of arsenic and chromium from entering the workplace and consumer products annually and represents one of the largest and most successful pollution prevention efforts in U.S. history.

Acid Copper Chromate (ACC). *However, the progress made is now being threatened.* In May 2006, the U.S. Environmental Protection Agency (EPA), under very heavy lobbying pressure, granted the Forest Products Research Laboratory[9] restricted use registration for wood preservative ACC (acid copper chromate) containing hexavalent chromium. EPA's decision allows ACC use for certain commercial wood products, but precludes its use for residential purposes. *FPRL, however, has applied for an unrestricted registration that would allow the company to sell ACC for use in all exterior wood products – including those used for residential, school and playground use.* The Pesticide Registration Improvement Act (PRIA) requires EPA to decide on ACC by January 20, 2007.

The chemical content of ACC and the chemistry of chromium in treated wood contribute to the risks associated with this wood preservative. First, ACC contains approximately 1.5 times the hexavalent chromium content of CCA. Secondly, the chemical conversion of hexavalent chromium (Cr^{+6}) to the less toxic trivalent form (Cr^{+3}) takes place at a much slower rate in ACC-treated wood than in CCA-treated wood. This process can take weeks or months and is especially slow in cold weather. EPA's risk assessment of ACC found that the reduction rate was highly variable and difficult to predict. This report addresses a number of risks posed by the hexavalent chromium in ACC and in ACC-treated wood, including:

- Hexavalent chromium (Cr^{+6}) is a known human carcinogen when inhaled. Workers in ACC-

[9] The Forest Products Research Laboratory is a private company and is not affiliated with the Forest Products Laboratory of the U.S. Forest Service (USDA).

treatment plants would have increased exposure to hexavalent chromium due to Cr^{+6} laden aerosols released during the treatment process. Woodworkers would also be exposed to increased Cr^{+6} levels in wood dust released from cutting and sanding operations. Chromium aerosols have also been associated with the induction of asthma.

- Hexavalent chromium is a potent cause of allergic reaction to the skin.[10] Numerous studies indicate that dermal exposures to hexavalent chromium (Cr^{+6}) can both cause sensitization and trigger serious allergic reactions at very low levels of exposure.[11]

In addition, exposures to Cr^{+6} will not be limited to consumers and workers but are likely to occur throughout the preservative's life cycle (from cradle to grave).

- Many Superfund sites, which have contaminated soil and groundwater, were created by treatment plants using hazardous chemicals including chromium. In April 2006, the California Regional Water Quality Control Board charged *Thunderbolt Wood Treating Company* in Riverbank, CA with multiple violations for chromium releases to soil, groundwater and surface water. This plant, until recently, treated wood with ACC for use in cooling towers. State and local officials are concerned that this chromium contamination may spread to municipal well fields where two wells have tested positive for chromium.

- *Discarded wood wastes*. Treated exterior wood structures have a useful lifespan on the order of ten years.[12,13,14] With widespread commercialization, ACC treated wood will within its first decade of use create hundreds of millions of cubic feet of waste containing high levels of chromium wastes. These wastes are likely to: (a) be classified as a hazardous waste; (b) require construction, renovation and demolition companies to meet costly hazardous waste management options; and, (c) add new enforcement responsibilities to state agencies without any guarantee of additional funding. Moreover:

    - ACC-treated wood wastes are likely to fail the *Toxicity Characteristics Leaching Procedure (TCLP)* and be classified as a hazardous waste due to ACC's high chromium content. This will require disposal in permitted hazardous waste landfills or hazardous waste incinerators and place a large enforcement burden on state regulatory agencies.

    - Because of an exception for arsenical pesticides initiated by EPA in the 1980's, CCA-treated wood is exempted from hazardous waste regulations even though it fails the TCLP test. ACC-treated wood (containing no arsenic) is not covered by the exemption.

    - Most of the waste is generated by construction, demolition and renovation contractors and is a major component of construction and demolition (C&D) debris. State regulations covering the disposal of CCA-treated wood wastes vary widely. Many sites allow treated wood wastes as part of C&D waste to be disposed in unlined landfills without groundwater monitoring.

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[10] For example, see Nethercott, et al., "A study of chromium induced allergic contact dermatitis with 54 volunteers; implications for environmental risk assessment, Occupational and Environmental Medicine, 1994, Vol. 51: pp. 371-380

[11] Nethercott study for example.

[12] McQueen, J. et al., *Forest Products Journal*, 1998, 48(11/12), 86-90.

[13] Alderman, D. et al., *Forest Products Journal,* 2003, 53(1), p. 38.

[14] Chemical Specialties, Inc., personal communication, September 2004

- *Incineration.* In some areas, waste wood is burned in incinerators and wood combustion boilers for energy. A recent study indicates that a high portion of chromium in the ash of wood treated with chromium-bearing wood preservative is in the highly toxic hexavalent form. The study also found that the leachate from this ash is mostly hexavalent.[15] The high portion of Cr^{+6} may occur because combustion oxidizes Cr^{+3} to Cr^{+6}. This finding has important implications with regard to the toxicity of ash and aerosols resulting from the burning of ACC-wood scraps and discards in backyard burners, wood stoves and fireplaces. EPA and company risk assessments have not addressed this issue.

The potential releases and risks of hexavalent chromium at many stages of the chemical's use are clearly preventable provided that EPA actions prohibit the use of ACC and encourage the use of widely available safer alternatives.

As described in subsequent sections, EPA has acknowledged that the commercialization of ACC would result in significant workplace risks. However, the Agency appears to be ignoring these risks as secondary concerns left to OSHA to address. Moreover, to our knowledge EPA's decision-making on ACC has not addressed issues pertaining to treatment plant releases or to massive future treated wood wastes that will meet the definition of a RCRA hazardous waste due to the leaching of chromium. EPA/OPP has focused nearly entirely on the role of hexavalent chromium as a skin allergen. In short, the agency has paid little attention to the merits of the across-the-board prevention of risks and hazardous materials/wastes management costs that would accrue by keeping hexavalent chromium out of the market place.

2.0 ACC: science and the regulatory process.

EPA's decision to allow the use of a hexavalent chromium-based preservative is based largely on data provided by the applicants and allied parties -- data that has not been subject to scientific peer review or public review. These studies have never been published nor peer reviewed, and have not been generally accessible to the public. The lack of independent review is a particularly serious issue with regard to hexavalent chromium, not only because of its toxicity but because there is recent evidence that industry consultants manipulated evidence in order to influence other chromium-related regulatory and court decisions. For example:

- A Washington Post article (February 24, 2006) describes a George Washington University / Public Citizen journal article documenting that scientists working for the chromium industry failed to report inhalation studies showing a five-fold increase in lung cancer deaths from moderate exposures to chromium. The Post article states that, "Company-sponsored scientists later reworked the data in a way that made the risk disappear." The apparent twisting of the science occurred at the same time that the chromium industry lobbied to block strict new OSHA limits for hexavalent chromium in workplace air.

- The *Journal of Occupational and Environmental* Medicine (JOEM) recently took the highly unusual step of retracting a 1997 article stating that the "financial and intellectual input to the paper by outside parties was not disclosed." The outside parties refer to consultants for PG&E who, according to investigative reports by the Wall Street Journal and the Environmental Working Group, manipulated data in the article in order to obscure a link between exposure to contaminated well water and the cancer death rate found by a Chinese scientist. This reverse JOEM article was cited by U.S. EPA in its 2001 assessment of hexavalent chromium in wood preservatives.

[15] Solo-Gabriele, H., et al., Arsenic and Chromium Speciation of Leachates from CCA-Treated Wood, (DRAFT), May 30, 2003, Florida Center for Solid and Hazardous Waste Management

State agencies, such as New Jersey and California, are now reexamining regulatory decisions based on data provided by various chromium interests. Such steps are critical given numerous regulatory decisions related to widespread chromium contamination in the workplace, soils and groundwater – decisions that are pending or that may need to be reopened.

As discussed in Section 4 below, EPA's Human Study Review Board (HSRB) strongly recommended that EPA reject procedures used by FPRL's consultant, Exponent, to selectively use and statistically manipulate the original data from its dermal allergy study – procedures which would increase the resulting minimal adverse effects level and weaken EPA's regulatory exposure level for hexavalent chromium on treated wood surfaces.

For these reasons, it is essential that EPA provide assurance to the public that EPA's decisions on ACC and other products are based on reliable data and assumptions and interpretations that are unbiased. EPA analyses should add appropriate margins of safety to cover limits and uncertainties in scientific information and to cover risks that are not addressed in detail by the Agency. Finally, all EPA analyses and studies generated by FPRL and its consultant(s) should be made available for review by the scientific community and public.

3.0 Inhalation risks

3.1 Inhalation risks at ACC-wood treatment plants. Hexavalent chromium (Cr^{+6}) is a known human carcinogen when inhaled. Workers in ACC-treatment plants would have increased exposure to hexavalent chromium due to Cr^{+6} laden aerosols released during the treatment process. EPA's recently concluded ACC analysis included an inhalation risk assessment. The results indicate that workers in ACC-wood treatment plants would be exposed to cancer risks well above EPA's acceptable range of 10^{-4} to 10^{-6}. Assuming that ACC were to reach a similar market share for residential use as did CCA (prior to the CCA phase-out), EPA estimates that equipment operators at the treatment plants would experience cancer risks as high in the 10^{-3} to 2×10^{-3}. These levels are an order of magnitude higher than the highest acceptable cancer risk.[16] However, EPA's findings are based on concentrations of chromium in air from only three (3) plants and the values were extrapolated from CCA plants. Thus, results are subject to large uncertainties, making the use of an adequate safety margins and uncertainty factor critical.

3.2 Inhalation risks among woodworkers. Woodworkers, especially those involved in sanding, cutting and lathing operations are exposed to wood dust in the air they breathe. According to EPA's ACC risk assessment, very high levels of hexavalent chromium persisted in ACC-treated wood for several months; in southern pine wood, Cr^{+6} was still present at concentrations ranging from 73 ppm and 134 ppm. Thus, equipment operators in woodworking plants would be exposed to dust containing these high concentrations of Cr^{+6}. EPA's risk assessment estimated that workers exposed to dust from ACC-treated southern pine would experience risks in the range of approximately 10^{-4} to 10^{-3} (1 per 10,000 to 1 per 1000). These levels are above EPA's highest acceptable cancer risk.[17] EPA's analysis of exposure is based on the assumption that

[16] May 30, 2006, Memorandum from Tim Leighton and Tim McMahon, Antimicrobials Division, OPP/ EPA, "Occupational and Residential Assessment of Individuals Exposed to Hexavalent Chromium (Cr^{+6}) in Acid Copper Chromate (ACC) Pressure-Treated Wood." to Mark Hartman.

[17] May 30, 2006, Memorandum from Tim Leighton and Tim McMahon, Antimicrobials Division, OPP/ EPA, "Occupational and Residential Assessment of Individuals Exposed to Hexavalent Chromium (Cr^{+6}) in Acid Copper Chromate (ACC) Pressure-Treated Wood." to Mark Hartman, p. 25-26.

woodworking plants are in compliance with OSHA standards for inhalation. However, it provides no data to support this assumption regarding the record, or the future assurance of, OSHA compliance at such plants. Thus, the analysis would underestimate risks in plants that are out of compliance with OSHA standards.

The mechanical forces involved in the sanding and sawing of treated wood has been shown to generate airborne particles that contain hexavalent chromium. Wood dust particles generated by sawing and sanding operations are large (~20 μm), and generally deposit in the slow clearance regions of the nasal cavity. The nasal cavity is a site at which an increased incidence of tumors has been associated with exposure to either inhaled untreated wood dust or hexavalent chromium.[18] Thus, there is a potential for synergism between deposited wood dust and metals in the nasal cavity.

To our knowledge, EPA has not made any assessment of potential chromium inhalation risks associated with home-based carpentry where OSHA protective standards do not apply and where children and other family members may be exposed.

4.0 Dermal Exposure. Numerous studies indicate that dermal exposures to hexavalent chromium (Cr^{+6}) can both cause sensitization (induction) and trigger serious allergic reactions (elicitation) at very low levels of exposure.[19] Hexavalent chromium is the second most common skin allergen in humans.[20] While the symptoms may be reversible, the underlying sensitization remains; additional exposures to Cr^{+6} cause repeated and often serious allergic reactions, e.g. blemished skin, rashes, redness, itching, severe discomfort, emotional distress and loss of work.

In order to make its decisions on wood preservatives and other pesticides, EPA reviews data submitted by manufacturers. With regard to dermal exposure and ACC, EPA is using several kinds of data: (a) "Wipe samples" obtained by rubbing a cloth over a wood surface to replicate the amount of Cr^{+6} retained on skin due to contact with treated wood; and, (b) various tests in which human subjects are exposed to a range of Cr^{+6} doses to estimate the minimal exposure that will cause an allergic response in individuals who are known to be sensitive to chromium. EPA uses results from the exposure study to designate an allowable level of exposure or "safe area dose" measured ug of Cr^{+6}/cm^2. In order to determine the risk associated dermal exposure to ACC-treated wood, EPA compares wipe sample results to the "safe area dose." This kind of comparison guides EPA's determination of allowable uses and restrictions. Clearly the choice of "safe area dose" is a critical determination.

4.1 "Safe area dose" / The Nethercott Study. EPA's May 2006 decision to issue a restricted use registration for ACC was based on an estimate of "safe area dose" made by agency's Office of Pesticide Programs (OPP) in August 2004. EPA used a "safe area dose" based on the results of a human exposure study known as the Nethercott Study[21], published in 1994. See Box 1.

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[18] See Decker et al., "Exposure to wood dust and heavy metals in workers using CCA pressure treated wood," AIHA Journal 63:166–171 (2002)

[19] For example, see Nethercott, et al., "A study of chromium induced allergic contact dermatitis with 54 volunteers; implications for environmental risk assessment, Occupational and Environmental Medicine, 1994, Vol. 51: pp. 371-380

[20] Haines, A. T. and Nieboer, E., 1988, "Chromium hypersensitivity." Adv. Environ. Science and Technology, Vol. 20, pp. 497-532.

[21] Nethercott, et al., "A study of chromium induced allergic contact dermatitis with 54 volunteers; implications for environmental risk assessment, Occupational and Environmental Medicine, 1994, Vol. 51: pp. 371-380

EPA's OPP originally recommended a "safe area dose" of 0.0018ugCr^{+6}/cm^2. This was obtained by taking the lowest observed adverse effect level (LOAEL) from the Nethercott Study of 0.018ug/cm^2 (See Box) and divided it by a total uncertainty factor of 10 to account for the relatively small sample size and the fact that the LOAEL is not the "no observed adverse effects level" or NOAEL.

Based on recommendations of the FIFRA Science Advisory Panel (May 2004), EPA decided to use a higher (less protective) measure of minimal response level known as the as the10%MET (10^{th} percentile Minimum Elicitation Level, See Box 1) derived from the Nethercott Study. This value was 0.089ug/cm^2. EPA retained an uncertainty factor of 10 and recommended a revised "safe area dose" of 0.009ug/cm^2. Further weakening of this dermal threshold level would likely help FPRL obtain an unrestricted registration for ACC.

Box 1: Nethercott Study

In this study, a group of 54 chromium-sensitized individuals were exposed to various doses (ug Cr^{+6}/cm^2) on their skin. Both OPP and EPA's FIFRA Scientific Advisory Panel (SAP) judged this study to be the only study available to be sufficiently large and well designed as a basis for determining safe area dose. The study used a technique known as patch tests. In these tests known quantities of Cr^{+2} were added to square patches (e.g. area 0.8 cm^2). The patches (with varying doses) were than applied and held to the skin with adhesive backing to ensure maximum contact and transfer of chromium from the patch to the skin via perspiration. This is known as a closed or occluded test due to the use of the patch.

This study provided two estimates: (a) the lowest observed adverse effect level (LOAEL) of 0.018 ug/cm^2, and (b) a10%MET level of 0.089 ug/ cm^2. This level is a statistical estimate of the exposure below which a cumulative total of 10 percent of exposed, sensitized individuals experienced a dermal response.

4.2 The ROAT Study. FPRL submitted a new study of dermal allergic response known as the Repeated Open Applications Test (ROAT).[22] This study of hexavalent chromium on human subjects was conducted by Exponent, a "product defense" firm contracted by FPRL. The term *open* refers to the application of the ACC test solution directly on the surface of skin without the use of a patch. Proponents of the ROAT argue that this test more realistically simulates consumer exposures to treated wood than patch testing. *Repeated* in this case refers to the application of doses on ten successive weekdays.[23]

Exponent presented four different estimates of 10%MET including several estimates based on

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[22] This study is not readily accessible to the public. However, a fairly detailed summary of the ROAT study is on an EPA website. McMahon, Tim, Antimicrobials Division, OPP / EPA, Data Evaluation Record, Skin Sensitization non-guideline (Repeat Open Application Test).

[23] All participants were first identified and confirmed to have been previously sensitized to hexavalent chromium except for a group of non-sensitive subjects used as a control.

selective use of data and/or statistical manipulation of the data, including:

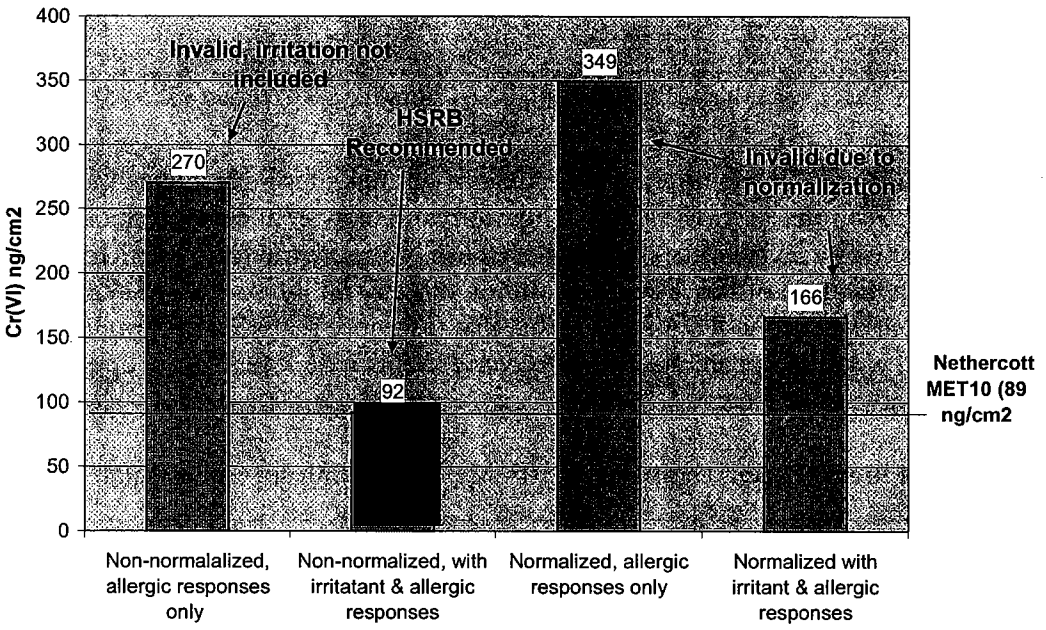
- Exclusion of skin outbreaks diagnosed as "irritations" (as opposed to allergic responses) from the database.
- Statistical adjustment based on normalizing the data against a national survey of patch test data.

The results are presented on the following table.

Table 1: ROAT and Nethercott 10%MET Estimates

Basis For 10% MET	All responses	Excluding responses diagnosed as irritation	10%MET units
Original Data	**0.092**	0.270	ug Cr^{+6}/cm^2
Normalized Data	0.166	0.349	ug Cr^{+6}/cm^2
Nethercott 10% MET	**0.089**		ug Cr^{+6}/cm^2

Figure 1: Comparison of 10%MET Levels from FPRL ROAT Study



As Table 1 and Figure 1 show, narrowing the database and statistical adjustment lead to much higher thresholds for allergic response. For example, excluding diagnoses of irritation and normalization yields a 10%MET of 0.349 as opposed to 0.092 for the complete, unadjusted

database, a nearly identical value to the original Nethercott 10%MET. As stated previously, higher threshold effects levels would enable EPA to set higher (less protective) regulatory levels.

Because the ROAT was performed using human subjects, it was subject to review by EPA's Human Studies Review Board (HSRB). In its October 18, 2006 meeting HSRB determined that the study in general was conducted in a scientific manner, but strongly and unanimously *rejected* Exponent's attempts to exclude responses diagnosed as irritation and to normalize the data against a previous database with little documentation on the individuals in the database.

To conform to the HSRB recommendations, EPA must use 0.092ug/cm^2 and exclude Exponent's adjusted estimates. As shown in the table, following the HSRB recommendation results in a 10%MET that has nearly the same result as that derived from the Nethercott patch test study (0.089 ug/cm^2). Thus, both values rounded give a 10%MET of 0.09. Dividing by an uncertainty factor of 10 yields EPA's previous "safe area dose" of 0.009.

4.3 Cr^{+6} Residues on ACC-Treated Wood. There is evidence that levels of hexavalent chromium samples on ACC-treated wood surfaces would exceed a "safe area dose" of 0.009ug/cm^2. A report submitted to EPA by a major manufacturer, Osmose, clearly shows that the Cr^{+6} to Cr^{+3} conversion rate is slow enough to expose workers and consumers handling ACC-treated wood to hexavalent chromium levels exceeding the 0.009ug/cm^2 level of concern for periods of weeks and months (depending on such factors as the kind of wood and curing temperature). EPA's own review of the Osmose report states that the data from this study *"do not suggest that holding time can adequately predict the level of dislodgeable Cr^{+6} on the surface of wood that has been treated with ACC. The internal levels of Cr^{+6} are reported to be highly variable, even among individual boards treated at the same time in one unit. This high variability does not allow for an estimation of the rate of reduction."* [24] Given the limited data available, regulators should presume that those in contact with ACC treated wood even after extended periods will be exposed to unconverted hexavalent chromium at levels capable of causing an allergic response in chromium-sensitive individuals.

4.4 Dermal Exposure at ACC Wood Treatment Plants. As stated previously, EPA risk assessment does not provide any estimates for worker risk due to probable daily contact with ACC treatment solution and mists. Instead the Assessment contains the following language:

> *"The majority of lumber/wood that is treated at a pressure treatment facility is moved mechanically (e.g., forklifts). However, there is the potential for dermal contact with this wood or surfaces that have Cr^{+6} residues (e.g., equipment near the pressure treatment cylinder door). It is EPA's policy to require personal protective equipment (PPE) such as gloves, long pants, long sleeved shirts, or coveralls for chemicals that are either dermal irritants or dermal sensitizers to mitigate the localized skin effects. It is recommended that ACC labels require this PPE."*[25]

This language is hardly reassuring and neglects evidence that clothing and gloves become contaminated with treatment solution constituents including hexavalent chromium. This may

[24] Leighton, Tim, U.S. EPA, OPP, Antimicrobials Division, Memorandum, "Review of the "Osmose ACC 50% Wood Preservative: Determination of Hexavalent Chromium Residuals In and On Wood Following Treatment with Acid Copper Chromate." May 30, 2006.

[25] May 30, 2006, Memorandum from Tim Leighton and Tim McMahon, "Occupational and Residential Assessment of Individuals Exposed to Hexavalent Chromium (Cr^{+6}) in Acid Copper Chromate (ACC) Pressure-Treated Wood." p. 27.

occur via condensation of liquid aerosols, spills or splashes during mixing or transfer of aqueous solutions. A study by Garrod (1999) [26] describes conditions in treatment plants as follows:

> *"...there are tasks through which timber pre-treatment process operators can become contaminated with preservative. Timber is placed onto a bogie for loading into the treatment vessel, which involves strapping down to prevent its flotation when fully immersed in preservative. Unless freshly cleaned, these bogies and restraining straps are contaminated. As the bogie is unloaded, residual preservative fluid dislodges from wet surfaces to work clothing. Residues also dislodge during routine maintenance activities, such as when the operator wipes the vessel door seals to remove material that impairs sealing, or checks the density of working solutions. Over time, preservative can spread further from the treatment vessel, into the work environment; and contact with contaminated surfaces occurs as operators work in the treatment zone, drive lift trucks, or move wet timber."* p.544.

The Garrod et al. study also found that coveralls and gloves worn by wood treatment workers were contaminated with hexavalent chromium. Even gloves, which prevented penetration, became contaminated (apparently when workers removed their gloves to manipulate equipment controls). The exposure to wet close conditions in which workers' clothing may become periodically moistened with treatment solution and the clothes may hold the liquid in close and prolonged contact with the skin. The presence of moisture may also facilitate the transfer of highly soluble Cr^{+6} through the outer epidermal layer to the cells involved in sensitization.

The findings of Garrod suggest that many workers will be exposed to dermal exposures that can last many hours on a daily basis over the course of their employment. This evidence also has implications with regard to hand-to-mouth contact and ingestion. Finally, hexavalent chromium may be brought home on clothing and thus expose family members.

Clearly, EPA's analysis presents no information or risk assessment with regard to dermal exposure of ACC-treatment plant workers. In this regard, the EPA's analysis is inconsistent with the more detailed treatment of inhalation risks and is inadequate to determine the dermal exposures and risks to which ACC-plant workers would be subjected if EPA grants FPRL an unrestricted use license.

4.5 Uncertainty Factors. As stated previously, EPA applies uncertainty factors to set determined doses or endpoints that have an adequate margin of safety. EPA has previously adhered to the standard default uncertainty factor of 10 for human variability to provide in establishing its "safe area dose" for dermal exposure to Cr^{+6}. Proponents of ACC have called for a smaller uncertainty factor given that two studies showed similar results. However, as discussed below, EPA's use of an uncertainty factor of less 10 would inappropriately lower the margin of safety. There are many limits to the two studies being considered: neither may adequately represent the populations of chromium-sensitized people in the U.S.; and neither may simulate all of the important dermal exposures likely to be experienced by workers and consumers if ACC gains unrestricted registration.

Standard EPA practices. For non-cancer effects, regulatory agencies such as EPA presume that there is a threshold dose below which no adverse effects will occur. To establish a threshold

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[26] A. N. I. Garrod, M. Martinez, J. Pearson, A. Proud and D. A. Rimmer. Exposure to Preservatives Used in the Industrial Pre-treatment of Timber, Ann. Occupational. Hygiene, Vol. 43, No. 8, pp. 543-555, 1999.

level, regulatory agencies determine critical effects (e.g. allergic response) with the lowest threshold and a study or studies that provide data sufficient to *estimate* threshold. Because of the inherent limits of studies (e.g. based on animals rather than people, based on very small samples compared to populations) regulatory agencies adjust experimental thresholds with a margin of safety to ensure that the allowable dose or concentration takes into account highly sensitive individuals in the larger population. Standard practice for animal-based studies is to divide a minimal threshold level (i.e. no-observed-adverse-effect levels [NOAELs] or lowest-observed adverse-effect levels [LOAELs]) by the product of two uncertainty factors. The usual default values are shown below:

- Interspecies uncertainty (due to differences between animal tested and humans): 10
- Intraspecies uncertainty[27] (due to variation among humans): 10
- Allowable concentration (reference concentration) = threshold / (10) (10) = threshold / 100

Since the Nethercott and ROAT studies are based on human subjects, the default uncertainty is:

- Allowable concentration = threshold / (10) (1) = threshold / 10

This is exactly what EPA did in November 2003 when it divided a LOAEL of 0.018 by 10 for a "safe area dose" of 0.0018 ug Cr^{+}/cm^2. In August 2004, the Agency used a similar technique but used the Nethercott 10%MET of 0.09 as the threshold – yielding an allowable dose of 0.009. In both cases the uncertainty factor applied was 10.

Although there has been some progress in replacing default values with chemical specific, such applications require extensive databases. According to experts in the field of risk assessment, little progress has been made in developing chemical specific uncertainty factors for sensitization.

There are a number of additional reasons to retain or increase the uncertainty factor used to designate EPA's allowable dose.

- The use of a 10%MET rather than a NOAELs or LOAELs affords less protection to the most vulnerable (sensitized) people. Note that the LOAEL in the Nethercott study ($0.018ug/cm^2$) was lower by a factor of 5 than the 10%MET for the same study. We also note that Exponent / FPRL study's lowest dose was 0.09 rather than the 0.018 dose used in the Nethercott study. This would have permitted a direct comparison between the studies. The use of 10%MET and the higher minimal dose in the ROAT study also demonstrate the need for a higher uncertainty factor.[28]

- The ROAT and Nethercott studies do not consider sensitization caused by oral ingestion of Cr^{+6}. Available evidence cited in EPA OPP documents suggest that Cr^{+6} may be a more

[27] Variability includes differences between people in the portion of an external dose that reaches affected cells (kinetic variation) and the individual differences in the toxicological response to an internal dose (dynamic variation).

[28] Also note an important difference between the Nethercott and ROAT studies. The Nethercott study used a range of Cr^{+6} patch test doses from 0.018 to 4.4-ug Cr^{+6}/ cm^2 (based on literature review of previous studies). Of the 54 subjects tested, 1 person had an allergic response at the lowest dose of 0.018 Cr^{+6}/ cm^2. Thus the LOAEL for this study was 0.018. On the other hand, the ROAT study's lowest dose was 0.09 $Cr^{+6}ug/cm^2$. At this dose, two subjects were diagnosed with allergic responses and 2 with irritations.[28] Thus, there is no way to know whether either allergic reactions or irritations would have occurred at doses lower than $0.09ug/cm^2$.

potent dermal sensitizer when taken orally than when applied dermally.[29] This is a key issue because workers or residents inadvertently ingest Cr+6 via hand to mouth contact.

- Neither the Nethercott nor ROAT tests may accurately represent serious exposures by workers in wood treatment plants – exposures that may last for entire work shifts and repeated on a daily basis. (See previous discussion of dermal exposure among treatment plant workers and evidence from Garrod [1999]). The role of prolonged, repeated moist contact has not been addressed in EPA's review document.

- *Are individuals with various skin afflictions more sensitive to Cr^{+6}?* The ROAT and Nethercott studies excluded individuals with skin abrasions and related conditions. Thus they provide no information on this subject and add to variability and the uncertainty of the findings.

- Several experts on the FIFRA SAP meeting on dermal sensitization stated that patch tests surveys miss large numbers of sensitive individuals who self-medicate with over-the-counter treatments (antihistamines and steroid creams), which affect sensitization.[30] Thus, the number of highly chromium-sensitized individuals may be larger than those indicated in national surveys, which are based on patch tests on individuals who seek medical help.

- A further limitation of the two studies is that all participants were over the age of 18. Thus, the study provides no information on dermal allergy threshold levels for children. Studies that would allow reliable evaluation of age as a factor are lacking. Patch tests are not routinely performed on infants and young children unless an allergy is suspected. Moreover, it is extremely difficult to draw conclusions based on comparisons between age groups when the data on the different age groups come from entirely different studies using entirely different study designs procedures.

- A recent study demonstrates regional differences in the sensitivity of individuals to dermal exposure to hexavalent chromium. [31]

The above discussion indicates that there are a number of sources of variability and uncertainty that have not been addressed in the studies currently being used by EPA to determine a threshold for allergic contact dermatitis. There is clearly insufficient information that would permit derivation of a chemical specific uncertainty factor to replace standard values, e.g. 10 or 100. (See recent journal article by Solecki.[32]) In the case of ACC's elicitation of dermal allergic

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[29] Evaluation of the Risk Assessment Methodologies Based on the Hexavalent Chromium [Cr (VI)]-Elicited Allergic Contact Dermatitis (ACD) in Sensitized Populations and MADEP's Recommendations; Massachusetts Department of Environmental Protection, July 1998. As cited in EPA, OPP Memorandum from Timothy F. McMahon, Ph.D. Chair, Antimicrobials Division Toxicity Endpoint Selection Committee Antimicrobials Division, Nov. 26, 2003. Moreover, Cr (VI) may be a more potent inducer of ACD when given orally or by inhalation than when applied dermally (Fregert, 1965; Glaser et al., 1985).

[30] FIFRA SAP Meeting, May 4, 2004, Transcript, pp. 293-296.

[31] Thompson, T and Belsito, D. "Regional Variation in Prevalence and Etiology of Allergic Contact Dermatitis": Amer. Journal Of Contact Dermatitis, Vol. 13, No. 4, Dec. 2002.

[32] Roland Solecki, et al. "Guidance on setting of acute reference dose (ARfD) for pesticides," Food and Chemical Toxicology 43 (2005) 1569–1593, www.elsevier.com/locate/foodchemtox

reactions, there is ample justification for a value higher than 10 and a lower dermal endpoint to establish allowable exposure for the most sensitive individuals exposed to ACC and ACC-treated wood.

However, it is also important to emphasize that there are also numerous data limitations and uncertainties with regard to the exposures to hexavalent chromium that can be expected if ACC receives an unrestricted use registration. Examples include inadequate information on:

- The rate of hexavalent chromium reduction in ACC-treated wood.
- The role of deck and bleaching and cleaning agents in re-oxidizing trivalent chromium to the hexavalent state. EPA acknowledges this issue citing an article by Taylor et al (2001). EPA states, however, "[T]here is insufficient information on this phenomenon to determine if there are any risks of concern." We would contend that this is another data gap, area of uncertainty, and reason for caution.
- The average and minimal periods between treatment and shipment of treated wood to suppliers.
- Data on the extent to which the wood treatment industry in order to assure efficacy over-treats such that concentrations of treatment constituents are greater than those specified and certified for the given uses.
- Risk assessment on potential hexavalent chromium exposures related to home carpentry and the burning of ACC-treated wood for outdoor cooking, campfires, disposal, fireplaces and wood stoves.

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