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January 29, 2007

The Honorable Stephen Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re. EPA Decision on Hexavalent Chromium and Memorandum
EPA-HQ-OPP-2006-0606

Dear Mr. Johnson:

We are writing to support EPA's decision to deny all applications for registration of acid copper chromate (ACC) as a wood preservative pesticide intended for residential use. At the same time, we ask that the agency withdraw its December 21, 2006 decision memorandum that proposes to weaken by a factor of fifty the reference dose for dermal exposure to ACC. The EPA memorandum virtually eliminates any margin of safety and acknowledgment of human variability regarding human exposure to hexavalent chromium as a result of ACC treated wood use. The use of this obsolete and dangerous wood preservation chemical and technology cannot be justified, given the wide availability and application of safer and cost competitive alternative chemicals, processes, and approaches.[1]

We request that EPA withdraw its December 21 memorandum, given our three main concerns:

?? The EPA memo implies that the Human Studies Review Board (HSRB) endorses a decision to weaken regulations for ACC, despite the fact that HSRB did not include consideration of uncertainty factors or safe levels of this deadly chemical.

?? The EPA, in its memo, fails to appropriately apply uncertainty factors with reference to the HSRB authority.

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[1] As you know, Beyond Pesticides objected in written and oral comments before HSRB in October 2006 to human testing with hexavalent chromium (and the use of resulting data) because EPA has not made the threshold showing that this wood preservation chemical and technology has societal benefit, in light of the availability of alternatives. There are readily available safer substitutes for ACC, including ACQ (a copper quaternary compound) that already has 70-80% of the market, and won an EPA green chemistry award (2002) for its ability to reduce chromate by replacing ACC. EPA said, "ACQ Preserve® (alkaline copper quaternary) wood preservative is an environmentally advanced formula designed to replace chromated copper arsenate (CCA) wood preservatives, which are being phased out because of their hazardous properties. ACQ Preserve® will eliminate the use of 40 million pounds of arsenic and 64 million pounds of hexavalent chromium. It also avoids the potential risks associated with producing, transporting, using, and disposing of arsenic and hexavalent chromium contained in CCA wood preservatives and CCA-treated wood." www.epa.gov/greenchemistry/pubs/pgcc/winners/dgca02.html

?? Had EPA, in its memo, used uncertainty factors consistent with its own policies, it would support the conclusion that the health risks of ACC are unacceptably high and its registration be denied.

Background: EPA's December 21, 2006 Memorandum:[2] "Hexavalent Chromium – Summary of issues related to Quantitation of Dermal Sensitization Risk from exposure to treated wood containing hexavalent chromium," by Timothy McMahon of the EPA Antimicrobials Division, reports 0.092 ?g/cm^2 Cr^{+6} as the value to be used for the dermal risk assessment of CrVI in ACC-treated wood. This value is 50-fold weaker than its determination in 2003 of 0.0018 ?g/cm^2.

In 2003, EPA relied on a study by Nethercott (1994) (reviewed by HSRB in May, 2006). EPA had selected the study LOAEL of 0.018 as a start point (the lowest dose tested), and then applied a total uncertainty factor of 10X: 3X for failure to identify a NOAEL, and 3X for the small study size. Thus, a value of 0.0018 ?g/cm^2 was used for a dermal risk assessment of CrVI in ACC-treated wood.[3]

In its 2006 revision, EPA relied on a recently submitted registrant study, referred to at the ROAT study[4] (Repeat Open Application Test), reviewed by the HSRB in October, 2006.[5] EPA selected the MET_{10} (a 10% minimum elicitation threshold) of 0.092 ?g/cm^2 as reference dose from the ROAT study, with no uncertainty factors – fifty fold weaker than the 2003 reference dose. Our concerns are detailed below:

?? **The HSRB appears to endorse the EPA memo regarding weaker ACC regulations.**

In the conclusion of its report, the EPA memorandum makes the following statement:

"The 10x uncertainty factor that was applied to the 10% MET value selected from the single occluded dose Nethercott study in 2004 is no longer needed. The value of 92 ng [0.092 ?g] Cr VI/cm^2 as recommended by the HSRB is a level of dermal exposure at which elicitation of allergic contact dermatitis is not expected to occur from repeated dermal contact with ACC-treated wood,

[2] EPA-HQ-OPP-2006-0606-Draft-0013

[3] EPA's December 21, 2006 Memorandum: "*Hexavalent Chromium* – Summary of issues related to Quantitation of Dermal Sensitization Risk from exposure to treated wood containing hexavalent chromium," by Timothy McMahon of the Antimicrobials Division. EPA-HQ-OPP-2006-0606-Draft-0013

[4] A Repeat Open Application Test (ROAT) was performed on 60 human study subjects who had been confirmed allergic to hexavalent chromium [Cr (VI)] through closed-patch testing. The purpose of this study was to develop a 10% minimum elicitation threshold value (MET10) for elicitation of allergic contact dermatitis for hexavalent chromium (as contained within the CopperShield® wood preservative treatment solution www.epa.gov/osa/hsrb/files/oct2006finaldraftreport120906.pdf

[5] HSRB draft report of October, 2006 meeting. www.epa.gov/osa/hsrb/files/oct2006finaldraftreport120906.pdf

and can be used for the dermal risk assessment of CrVI in ACC-treated wood as the updated 10% MET."[6]

This statement may readily suggest to the reader that HSRB endorses the regulatory reference dose of 0.092ug/cm^2. In fact, HSRB did not recommend a reference dose, but only made recommendations with regard to a 10%MET. HSRB recommended a 10%MET value of 0.092 ?g Cr^{+6}/cm^2 and rejected higher estimates based on (a) exclusion of responses judged to be irritation and (b) normalization. We are concerned that EPA's language (quoted above) blurs the distinction between the 10%MET and the regulatory action level. Moreover, the language is inaccurate in its claim that the 10%MET is level at which "*elicitation of allergic contact dermatitis is not expected to occur."* Nor did HSRB ever make this assertion as the language suggests. By definition the 10%MET is not a *no observed adverse effects level* (NOAEL), but an estimated level below which about 10% of sensitized individuals would experience a skin reaction if exposed to this level dermally.

?? **The EPA, in its memo, fails to appropriately apply uncertainty factors with reference to the HSRB authority.**

HSRB had no role in EPA's failure to apply uncertainty/safety factors to its MET_{10} study value.[7] Nonetheless, EPA's report concludes that the 10X uncertainty factor "is no longer needed" and that the 10%MET value of 0.092 ?g Cr VI)/cm^2 **"***as recommended by the HSRB is a level of dermal exposure at which elicitation of allergic contact dermatitis is not expected to occur from repeated dermal contact with ACC-treated wood."*[8] This language inappropriately suggests that HSRB endorsed the removal of an uncertainty factor. In fact, HSRB drew no conclusions on uncertainty factors.

?? **Had EPA, in its memo, used uncertainty factors consistent with its own policies, it would support the conclusion that the health risks of ACC are unacceptably high and the registration be denied.**

EPA (2006) reports 0.092 ?g/cm^2 Cr^{+6} as the value to be used for the dermal risk assessment of CrVI in ACC-treated wood and decisions on ACC registration. This value is 50-fold weaker than its determination in 2003 of 0.0018 ?g/cm^2.[9] Were EPA to follow its

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[6] EPA-HQ-OPP-2006-0606-Draft-0013

[7] The charge from EPA to the HSRB is to "comment on whether this study is sufficiently sound, from a scientific perspective, to be used to estimate a safe level of repeated dermal exposure to residues of ACC on treated wood." www.epa.gov/osa/hsrb/files/oct2006finaldraftreport120906.pdf

[8] EPA's December 21, 2006 Memorandum: "*Hexavalent Chromium* – Summary of issues related to Quantitation of Dermal Sensitization Risk from exposure to treated wood containing hexavalent chromium," by Timothy McMahon of the Antimicrobials Division

[9] EPA-HQ-OPP-2006-0606-Draft-0013

own guidelines and apply an uncertainty factor of 10X for intraspecies (human to human) variation, and an uncertainty factor of 3X for database weaknesses, the value would be:

0.092/30 = 0.0030 ?g/cm^2 Cr^{+6}, very similar to the earlier (2004) value of 0.0018 ?g/cm^2 Cr^{+6}. Weaknesses in the study design include: the study was not blinded, all controls were female whereas 42% (25) of the sensitized group was male, and there was an unexplained gender discrepancy in the severity of allergic responses.[10] EPA's decision to eliminate the uncertainty factor removes any margin of safety in the regulatory reference dose.

Moreover, the agency's logic is faulty. It is based mainly on additional information on repeated applications from the ROAT study. However, as the Agency has acknowledged, there are many sources of *intraspecies* variability and uncertainty other than repeated exposure. The ROAT study does not replicate all conditions of exposure, such as that experienced by workers in wood treatment plants whose clothes get soaked with treatment solution repeatedly and potentially for much longer periods than 10 days. This is documented in a study by Garrod.[11] EPA has also acknowledged that there is enormous variability and uncertainty regarding the decline of hexavalent chromium residues on ACC-treated wood surfaces as a function of post-treatment time.[12]

Conclusion

We request that EPA withdraw its December 21 memorandum, which sets an unacceptable precedent that could have paved the way for the agency's allowance of the hexavalent chromium-based wood treatment chemical ACC for residential uses, including for

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[10] HSRB draft report of October, 2006 meeting. www.epa.gov/osa/hsrb/files/oct2006finaldraftreport120906.pdf

[11] A study by Garrod (1999) 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 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.

[12] 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.

backyard decks, playground equipment, and picnic tables. The approval of ACC for residential uses would expose tens of millions of Americans to this hazardous chemical,

including millions who are especially sensitive to hexavalent chromium. In addition to the dermal effects discussed in this letter, we are deeply concerned that EPA has not conducted adequate review of a chemical that is known to cause cancer and non-cancer respiratory ailments, kidney and liver damage.

In light of the health risks to the general population, children, and workers, and given the availability of less toxic alternatives, we assert that the registrant could not meet its burden of showing that the pesticide does not pose an unreasonable risk of adverse effects, when considering the risks and benefits of its use. Registration and use of ACC is unjustified and we support EPA's denial.

It is important that EPA correct the record and respond to the inaccuracies in its memorandum of December 21, 2006, as the agency moves ahead with its denial of ACC registration and as it reviews future registration or reregistration requests.

Thank you very much for your consideration and attention to this matter.

Sincerely,

Jay Feldman
Executive Director

cc: Celia B. Fisher, Ph.D, Chairperson, HSRB
Mr. Jim Gulliford, EPA Assistant Administrator
Ms. Susan Hazen, EPA Deputy Assistant Administrator
Mr. Mark Hartman, Antimicrobials Division, OPP/EPA
Dr. Paul Lewis, EPA, Designated Federal Officer HSRB