

EPA SUBJECTS WOOD PRESERVATIVES TO MORE SOPHISTICATED ASSESSMENT

The U.S. Environmental Protection Agency's Antimicrobial Division is responsible for the registration and evaluation of wood preservatives that target fungi and other microorganisms. Until recently, wood preservatives were subject to a relatively modest set of data requirements, including a 90-day study; a teratogenicity study in one species; mutagenicity battery; and acute studies for labeling purposes. Minimal environmental fate and toxicology data also were required.

Over the past two years, several factors have pressed EPA to take a more aggressive approach toward risk assessment for wood preservatives. First, there has been widespread product liability litigation over chromated copper arsenate (CCA), and, more recently, creosote treated wood. The plaintiffs' attorneys in these actions are seeking "class certification" which, under the U.S. legal system, would allow them to represent all people in the nation that have allegedly suffered similar harm. Second, advocacy groups, such as Beyond Pesticides and the Environmental Working Group, have claimed that EPA is not doing adequate assessments of exposures that users of treated wood may have to the treatment chemicals. Finally, news media have picked up stories about the alleged dangers from preserved wood, heightening public interest in the issue.

In response to all of these pressures, EPA has begun to look more carefully at possible exposures to wood preservative chemicals from using treated wood. EPA is now assessing the likely environmental effects of preservative leaching from treated wood and the potential effects contact with preservative residue on wood has on humans. Today, registration of a new wood preservative will require not only the studies described above, but also studies on surface residue, likely exposures and, possibly, additional toxicity and environmental fate data. In a somewhat similar development, wood preservatives due for review in the European Union in March 2004 will need to be supported by an extensive data package including risk assessments for workers, users and the environment. The Agency uses this information to perform a health risk assessment based upon the proposed uses of wood treated with any new preservative. At a meeting of the EPA pesticide Science Advisory Panel (SAP) in August, EPA requested comment on using the Stochastic Human Exposure and Dose Simulation (SHEDS) Model developed by its Office of Research and Development, in assessing exposures to preservative residue from pressure treated wood. The EPA has proposed a streamlined version of the model, known as SHEDS Wood, for these analyses. The SHEDS Model and references can be found at <http://www.epa.gov/scipoly/sap/index.htm>.

Any applicant seeking to register a new wood preservative would be well served by anticipating EPA's new data requirements and risk assessment methodology. It will be much easier to obtain a registration if the applicant has performed both the studies EPA now will require and also its own assessment of potential risks similar to that done by EPA.

The new data requirements and approach to risk assessment that EPA is now applying to wood preservatives presents challenges and opportunities to companies seeking to market wood preservatives in the United States. The marketplace is in a state of change. A thoughtful regulatory and stewardship strategy can be very helpful in getting preservatives to market relatively quickly and in avoiding future regulatory or liability issues.

How can Steptoe and Johnson LLP help?

Steptoe has unparalleled expertise in wood preservative registration and risk assessment. We assist applicants and registrants in developing and implementing regulatory and testing strategies to accomplish their commercial goals for wood preservatives. For further information please contact: Seth Goldberg

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