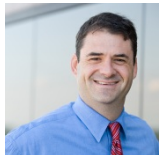



Law of the Little: Federal Court Sends Conditional Registrations of Nanosilver Pesticides Back to EPA



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Swiss company HeiQ Materials proposed to use new pesticides AGS-20 and AGS-20 (U) on manufactured textiles such as clothing, blankets, and carpet. Nanosilver is used in the pesticides to suppress microbes that cause odors and stains. The U.S. Environmental Protection Agency (EPA) granted conditional registration of the pesticides under the Federal Insecticide, Fungicide and Rodenticide Act, but a federal appeals court has now vacated part of EPA's decision and remanded the case back to the agency.

The Natural Resources Defense Council (NRDC) challenged the nanosilver pesticide registrations on several grounds involving EPA's risk analyses and decision to grant the registrations. NRDC's claims focused on potential risks to consumers who use textiles treated with AGS-20. A majority of the three-judge panel of the United States Court of Appeals for the Ninth Circuit rejected NRDC's primary challenges, finding the record supported two aspects of EPA's assessment methodology: (1) EPA's decision to use the characteristics of toddlers, rather than infants, as the subpopulation with the greatest risk of exposure; and (2) EPA's decision not to consider additional sources of exposure to nanosilver as part of the AG-20 risk assessment. These two conclusions were hotly contested by the dissenting judge, who questioned the evidence to support the findings. The dissent also suggested that these findings should be disregarded because they were not essential to the Court's decision to vacate EPA's conditional registration of the nanosilver pesticides.

Where EPA erred, according to all judges on the panel, was in applying EPA's own risk analysis guidelines. When deciding whether exposure to a pesticide might cause an adverse effect on humans, EPA first calculates a margin of exposure ("MOE") target. For example, an MOE target of 10 translates to human exposure that is 10 times lower than the

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lowest dose expected to cause an adverse effect. A higher MOE score therefore suggests less cause for concern, because it provides a wider margin of safety. The target MOE incorporates a margin of safety to account for uncertainties in the assessment of pesticide risk, such as incomplete toxicity data, differential human sensitivity to pesticides, and uncertainty in extrapolating from animal studies.

In this case, EPA determined that a risk concern would be present with an MOE of 1,000 or less. When determining the actual (predicted) MOE score for AG-20 under various exposure scenarios, EPA calculated MOE's between 1,000 and 3,600. EPA interpreted the MOE's to suggest no cause for concern from exposure to AG-20. But the Court held that EPA ignored its own guideline that the new pesticides would pose a risk concern with a MOE less than or equal to 1,000. The Court vacated EPA's decision based "solely on the fact that EPA's own rule states that there is a risk concern requiring mitigation when the calculated MOE is less than or equal to 1,000 and, under these circumstances, the actual MOE equals 1,000."

The Court rejected EPA's argument that an MOE in the neighborhood of 1,000 does not mean that consumers are actually at risk: "Although EPA's point is well taken as a practical matter, it is irrelevant as a legal matter." The Court also rejected EPA's argument that the true MOE actually exceeds 1,000 when calculated without rounding: "EPA's data is not precise enough to allow it to 'unround.'"

Going Forward

Even before the NRDC lawsuit was decided, EPA had already adjusted its risk assessment methodologies to consider children between six months and three years old when reviewing new applications for conditional registration. EPA had also planned to make further changes in response to an August 2013 report by the U.S. General Accountability Office, which recommended steps to improve the oversight of conditional registrations.

Though EPA's conditional registrations of AG-20 were vacated (at least in part), the Court's decision rests on the mundane proposition that a regulatory agency generally must follow its own rules. The Ninth Circuit's decision in the NRDC lawsuit – especially the deferential review applied in the majority's opinion dated November 7, 2013 – suggests that future conditional registrations of pesticides using nanoparticles will stand a good chance of being upheld so long as EPA diligently follows its own decision criteria.

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