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Narrow Critique Does Not Alter EPA Nano Risk Assessment

Law360, New York (November 26, 2013, 7:11 PM ET) -- When the Natural Resources Defense Council sued the U.S. Environmental Protection Agency immediately after the EPA conditionally registered HeiQ AGS-20 and AGS-20 U nanosilver pesticide products, the nano community collectively held its breath. On Nov. 7, 2013, that same community let out a collective sigh of relief as the U.S. Court of Appeals for the Ninth Circuit largely upheld the EPA's approach under the Federal Insecticide, Fungicide and Rodenticide Act in registering the first recognized nanopesticide.

The court vacated the EPA's decision on an extraordinarily narrow ground that has no general implications for nanopesticides. The court held that the EPA did not abide by its own rule requiring risk mitigation for a margin of exposure ("MOE") less than or equal to 1,000 when it concluded that there was "no risk concern requiring mitigation" for aggregate oral and dermal exposure to textiles treated with AGS-20 based on a reported MOE of exactly 1,000.

The opinion by a majority of the panel stated that this holding had no effect on "any portion of [the] EPA's decision where the calculated MOE is greater than 1,000." The majority opinion denied the NRDC's principal objections to the registration decision, holding that substantial evidence supported the EPA's decision to use the characteristics of toddlers rather than infants in its risk assessment for AGS-20, as well as the agency's decision not to consider other sources of exposure to nanosilver in its risk assessment. In a dissenting opinion, one member of the panel disagreed with the decision by the majority to deny these other objections.

The decision is available at: http://cdn.ca9.uscourts.gov/datastore/opinions/2013/11/07/12-70268.pdf

Background

In Dec. 2011, the EPA announced that it was conditionally registering a pesticide product containing nanosilver as a new active ingredient. HeiQ AGS-20 is a silver-based antimicrobial product approved for use as a preservative for textiles. As a condition of registration, the EPA required HeiQ to develop and to submit additional data to confirm the agency's initial determination that AGS-20 would not cause unreasonable adverse effects on human health or the environment.

The NRDC's Lawsuit

On Jan. 26, 2012, the NRDC filed suit in the U.S. Court of Appeals for the Ninth Circuit challenging the FIFRA registration of AGS-20. The NRDC argued that the EPA should not have allowed use of AGS-20 in clothing, baby blankets and other textiles "without the legally-required data about its suspected harmful effects on humans and wildlife." The NRDC challenged the EPA's actions under FIFRA section 16(b),

which allows “any person” who claims to be adversely affected by an EPA order issued after a “public hearing” to obtain judicial review “praying that the order be set aside in whole or in part.” Courts have construed a process in which EPA solicits public comment and compiles a record to constitute a public hearing within the meaning of this provision.

In its April 16, 2012, brief, the NRDC argued that the EPA’s decision to conditionally register AGS-20 was not supported by substantial evidence. The NRDC argued that the EPA should have considered exposure by infants in its risk assessment, and that this “would have shown that AGS-20 poses unacceptable risks, and thus may have ‘unreasonable adverse effects.’” The NRDC also argued that the EPA should have considered the risk from aggregate exposure to AGS-20 along with other sources of nanosilver and that such an assessment would have also shown that registering AGS-20 presented unacceptable risks.

On June 14, 2012, the EPA filed a brief arguing that its decision was supported by substantial evidence. According to the EPA, it “conservatively estimated potential consumer exposure to nanosilver from HeiQ AGS-20, assuming, among other things, that 35 percent of the silver contained in an AGS-20 treated textile that is chewed or worn could be ingested or absorbed as nanosilver, and that a three-year-old child could be exposed to a new textile daily for six months.” With respect to aggregate exposure to nanosilver from sources other than AGS-20, the EPA argued that “FIFRA neither requires aggregation nor specifies when aggregation might be appropriate,” and that the decision not to address other sources of nanosilver was appropriate “because there was no data indicating that any other products contain nanosilver that is chemically similar to the nanosilver in AGS-20.”

On Aug. 7, 2013, the court ordered supplemental briefs addressing the EPA’s determination that aggregate oral and dermal exposure when AGS-20 is used as a surface treatment does not present a risk concern even though the EPA calculated an MOE for this exposure of exactly 1,000. The EPA’s Aug. 21, 2013, supplemental brief argued that the precise aggregate MOE for this scenario prior to rounding was 1,006, which is greater than the target MOE of 1,000 or less. The EPA also argued that the MOE was based on conservative assumptions that likely overestimate the amount of nanosilver exposure.
The NRDC argued in its Aug. 29, 2013, supplemental brief that, given a calculated MOE of 1,000, which is not greater than the target MOE of 1,000, the EPA’s decision criterion dictates a finding that the risk is of concern and mitigation is required. In its Sept. 5, 2013, reply brief, the EPA reiterated its view that its risk assessment is reasonable and adhered to the MOE framework guidelines in this case, regardless of whether the aggregate MOE is 1,000 or 1,006.

The Court’s Decision

In the majority opinion by Circuit Judge Jay Bybee, the court first determined that the NRDC had demonstrated that its members have article III standing to challenge the conditional registration of AGS-20, because there is “a ‘credible threat’ that a probabilistic harm will materialize” and the alleged risk of injury is not too speculative to confer standing.

The court then addressed three potential objections to the EPA decision to conditionally register AGS-20. With respect to the two principal objections that were originally raised by the NRDC, the court found that the EPA decision was supported by substantial evidence, but the court also found that the EPA’s decision with respect to the specific issue addressed by the supplemental briefing was not supported by substantial evidence and vacated that part of the decision. Specifically, the court found that the EPA did not follow its own “rule of decision,” under which “there is a risk concern requiring mitigation when the short- or intermediate-term MOE is less than or equal to 1,000.”

The court rejected the EPA's argument that the MOE was actually 1,006, which it found to be based on a methodology that did not properly apply conventional rules for rounding. The court also rejected the EPA's argument that the calculated MOE of exactly 1,000 was based on very conservative assumptions and that an MOE near 1,000 is acceptable, stating that "[a]lthough [the] EPA's point is well taken as a practical matter, it is irrelevant as a legal matter." Noting that the rule of decision was created by tjhe EPA rather than the court, the court stated that it could not "revise [the] EPA's assumptions, alter its rule of decision, or perform our own risk assessment."

The majority opinion found that there was substantial evidence supporting the EPA's decision to use three-year-olds rather than infants in its risk assessment. The court stated: "Infants are more vulnerable because they weigh less, but toddlers are more vulnerable because they can chew fabric aggressively." The court acknowledged that there could be a "reasonable basis for disagreement" on this issue, but found there was substantial evidence supporting the choice as made by the EPA.

The court also found that there was substantial evidence supporting the EPA's decision not to include other sources of nanosilver exposure in its risk assessment for AGS-20. The court stated that "Congress expressly required aggregate risk assessment for food-use pesticides," but did not impose a similar requirement for pesticides not resulting in residues in food. The court also noted that the EPA has treated the nanosilver in AGS-20 as a "new active ingredient," and that the EPA could reasonably conclude based on the available information that "other types of nanosilver might not be chemically similar to AGS-20" or that consumers may not "be exposed to them in the same way in meaningful quantities."

A dissenting opinion argued that all members of the panel found one aspect of the EPA decision was flawed, so the court should have vacated the registrations issued in reliance on that decision rather than only purporting to vacate a part of the decision. The dissenting opinion argued that it was inappropriate for the court partially to deny and partially to grant the petition, that the court did not need to rule specifically on the NRDC's additional objections, and that the court ruled incorrectly on the merits of these additional objections. The majority opinion responded to the dissent by construing FIFRA Section 16(b) to require that the court resolve "all of the arguments presented by the party petitioning for review …"

Analysis

The sole basis given by the court for its decision is exquisitely narrow. The court has essentially stated that the EPA itself established binding rules for its decision and that the EPA is obligated to follow its own rules. Nevertheless, we expect that EPA scientists may be frustrated by the implicit premise of this narrow ruling that an MOE of 1,000 can be meaningfully distinguished from an MOE of 1,001. The narrow basis for the decision suggests that the EPA may be able to refine its risk assessment in a way that results in an MOE exceeding 1,000.

For example, HeiQ has been developing additional data since the registration was granted and this data might alter one or more assumptions underlying the risk assessment. In the alternative, the EPA and HeiQ may be able to agree on some form of risk mitigation that would incrementally increase the calculated MOE without materially impacting the commercial value of the product.

Given the narrow ground for the decision and its applicability to risk assessment in general, it appears unlikely that this decision itself will have broad significance for the EPA's regulation of nanomaterials. Nevertheless, it is possible that the issues on remand will ultimately be broader than the single narrow

question identified by the court. The EPA has stated its intention to evaluate the characteristics of registered pesticide products that contain metallic silver or silver compounds in the ongoing registration review process, and this may influence how the EPA decides to regulate products containing nanosilver.

The practical effect of the court's ruling is a bit unclear. Although the court only vacated a part of the EPA decision supporting conditional registration of AGS-20, that part of the decision was an essential constituent element in the EPA's rationale for granting the registrations. Accordingly, a reasonable construction of the court's action is that the HeiQ registrations themselves have been vacated, pending EPA actions on remand that address and resolve the specific problem identified by the court.

Having said this, we note that the court also specifically ruled against two principal objections as originally articulated by the NRDC in its petition for review. The NRDC may be able to renew these objections in the event the EPA decides on remand to reissue the registrations, but the NRDC will need to argue that the EPA has new pertinent information or that the record assembled during remand otherwise provides new grounds for these objections.

On the whole, the EPA, HeiQ and nano stakeholders have reason to be pleased with the decision. The court's narrow critique of the EPA decision has no evident effect on the general methodology that the EPA has adopted for evaluating and registering nanopesticides. The EPA's general approach concerning nanopesticides was validated by the court, and there is no reason to anticipate that the remand will alter the ultimate commercial integrity of the HeiQ pesticide products.

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