
APPELLATE COURT VACATES CONDITIONAL NANOSILVER REGISTRATION

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On May 30, 2017, the U.S. Court of Appeals for the Ninth Circuit responded to two petitions for review of the U.S. Environmental Protection Agency's (EPA) conditional registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of a nanosilver pesticide product and vacated that conditional registration. *NRDC v. EPA*, No. 15-72308. The Natural Resources Defense Council (NRDC), the Center for Food Safety (CFS), and the International Center for Technology Assessment (ICTA) filed petitions in 2015 asking the court to set aside EPA's final order granting a conditional registration for a nanosilver-containing antimicrobial pesticide product named NSPW-L30SWS (NSPW). The court vacated the conditional registration because, according to the court, "EPA failed to support its finding that NSPW was in the public interest."

Background

On May 19, 2015, EPA issued a conditional registration for NSPW-L30SWS. According to EPA's Office of Pesticide Programs, the product would be used as a non-food-contact preservative to protect plastics and textiles from odor- and stain-causing bacteria, fungi, mold, and mildew. Items to be treated included household items, electronics, sports gear, hospital equipment, bathroom fixtures, and accessories. EPA based its decision "on its evaluation of the hazard of nanosilver after reviewing exposure data and other information on nanosilver from the applicant, as well as data from the scientific literature." EPA stated that these data show that treated plastics and textiles release "exceedingly small amounts of silver." Based on this evaluation, EPA "determined that NSPW-L30SS will not cause unreasonable adverse effects on people, including children, or the environment and that it would be beneficial because it will

introduce less silver into the environment than competing products." EPA noted that it is requiring the company "to generate additional data to refine the Agency's exposure estimates."

On July 27, 2015, NRDC filed a petition in the U.S. Court of Appeals for the Ninth Circuit (Case Number 15-72308), and CFS and ICTA filed a second petition (Case Number 15-72312). Both petitions asked the court to set aside EPA's final order granting a conditional registration for NSPW.

NRDC had previously challenged EPA's first decision to grant a conditional registration for a product characterized as a nanosilver product, which was granted to HeiQ in 2011. On November 7, 2013, the U.S. Court of Appeals for the Ninth Circuit granted in part and denied in part NRDC's petition for review of HeiQ AGS-20 and AGS-20 U (collectively, AGS-20). The court held that "substantial evidence" supported EPA's decision to use the characteristics of toddlers rather than infants in determining whether AGS-20 placed consumers at risk. The court vacated EPA's decision "insofar as it concluded that there was no risk concern requiring mitigation for short- and intermediate-term aggregate oral and dermal exposure to textiles that are surface-coated with AGS-20."

Issue before the Court

When EPA granted another conditional registration for NSPW, EPA found that granting it was in the public interest. EPA made this finding on the basis that NSPW had a lower application rate and a lower mobility rate when compared to conventional (non-nano)-silver pesticides, and thus had the potential to reduce environmental loading and risk caused by the release of silver into the environment. Petitioners disputed these facts. EPA also found that the registrant had insufficient time to generate the data required for unconditional registration. Petitioners also challenged this finding, but the court reached a decision without considering this argument.

Court's Decision

The court stated that it was unaware of any prior decision considering the public interest requirement under FIFRA section 3(c)(7)(C). The court reviewed the statutory background of the provision and then considered whether EPA had supported its public interest finding for NSPW with substantial evidence. The court stated that, under FIFRA section 3(c)(7)(C):

[EPA] may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the [EPA] first imposed the data requirement) on the condition that by the end of such period the [EPA] receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the [EPA] may prescribe. A conditional registration under this subparagraph shall be granted only if the [EPA] determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and *that use of the pesticide is in the public interest*. [Emphasis added.]

According to the court, the public interest requirement reflects an important distinction between conditional registration and unconditional registration. EPA can temporarily register a pesticide “with less-than-complete risk data so long as the EPA, among other additional requirements, determines ‘that use of the pesticide is in the public interest.’” The court reviewed the legislative history of the public interest requirement, stating that Senator Leahy, “who sponsored the bill that created the conditional registration provision, stated that the Senate committee carefully considered the statutory requirements so conditional registration ‘would be reserved to the truly exceptional case.’” The court also noted the testimony of former EPA

Administrator Douglas Costle, who stated that there “may be a real need for use of the pesticide to avoid pest outbreaks. It is our opinion that in some of these cases it would be proper to allow conditional registration . . . if the public interest would be served by issuance of a conditional registration, bearing in mind the benefits as well as the likely scope of the risk. Although we think that the exercise of this conditional registration authority for new chemicals would be rare, we feel that it should be available in appropriate cases.”

When considering the registration application, EPA found that use of NSPW is in the public interest because it has the “potential” to reduce the amount of silver released into the environment. The petitioners challenged the factual premises underlying EPA’s public interest finding:

- (1) That NSPW has a lower application rate (i.e., it uses less silver) than conventional-silver pesticides;
- (2) That NSPW has a lower mobility rate (i.e., it is less likely to release silver into the environment in detectable quantities); and
- (3) That current users of conventional-silver pesticides will switch to NSPW and/or that NSPW will not be incorporated into new products.

While the court found that substantial evidence supports EPA’s findings that NSPW has lower application and mobility rates, the court agreed that the third premise, that current users of conventional-silver pesticides will switch to NSPW and/or that NSPW will not be incorporated into new products, “impermissibly relies on unsubstantiated assumptions.” According to the court, EPA cited no evidence in the record to support its assumption that current users of conventional-silver pesticides will switch to NSPW (“the substitution assumption”), but contends that it will occur as a “logical matter.” The court stated that the lack of evidence supporting the substitution assumption is problematic in light of EPA’s other

unsupported assumption, that there will be no new products. The court noted that EPA assumes current users of conventional-silver pesticides will switch to NSPW because of its benefits, but that these same benefits will not prompt manufacturers to incorporate NSPW into new products. EPA could have proved these assumptions, but without evidence in the record to support the assumptions, the court stated that it “cannot find that the EPA’s public-interest finding is supported by substantial evidence as required by FIFRA.” According to the court, the public interest finding is an “essential prerequisite to conditional registration,” and EPA failed to support that finding for NSPW with substantial evidence. The court vacated the conditional registration in whole, and did not consider the remaining issues raised by petitioners.

Discussion

While the court’s 2013 decision regarding the conditional registration for AGS-20 was decided on a very narrow, case-specific issue, this decision is broader in scope and could have significance for EPA’s issuance of conditional registrations under FIFRA. In 2013, the court vacated EPA’s decision granting a conditional registration to HeiQ “insofar as it concluded that there was no risk concern requiring mitigation for short- and intermediate-term aggregate oral and dermal exposure to textiles that are surface-coated with AGS-20.” Here, the court reviewed the statutory background of the public interest provision and ruled that EPA failed to provide sufficient evidence to support its finding that granting a conditional registration for NSPW was in the public interest. The briefs were filed and the case was argued under the Obama administration, and it remains to be seen how the Trump administration will respond.

Because the court vacated the registration for NSPW, pending further review by EPA on remand, EPA would consider continued commercial sale and distribution of NSPW unlawful. To effectuate the court’s decision, EPA will need to devise an orderly process for removing stocks of NSPW from channels of trade. This may involve issuance of a

Stop Sale, Use, and Removal Order under FIFRA section 13.

The decision’s broadest application is a logical outgrowth of the policy decision that EPA made years ago that it will classify the nanosilver in each “new” product formulation as a new active ingredient, rather than presuming that all nanosilver contained in any registered pesticide is a single active ingredient. EPA also has not yet determined whether it will classify the colloidal elemental silver contained in many existing registered pesticides as nanosilver, although it appears to satisfy the EPA definition.

EPA’s decision to classify each new nanosilver product as a new active ingredient means that EPA must satisfy the more stringent “public interest” criterion to grant a conditional registration for each and every new nanosilver product. This significant threshold requirement may well discourage applicants to register innovative new nanosilver products, even where such products would supplant existing nanosilver or conventional silver products that may entail greater human or environmental exposures. Stakeholders may wish to consider urging EPA to reconsider its policy of classifying each new nanosilver formulation as a new active ingredient or otherwise to amend its current position to ensure innovation is not impeded.

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