

Ninth Circuit Invalidates Nanosilver Conditional Pesticide Registration

June 2017

On May 30, 2017, in a decision that could significantly impact registrants of new pesticide products, the U.S. Court of Appeals for the Ninth Circuit vacated the Environmental Protection Agency's (EPA) conditional registration of a nanosilver-based pesticide product on the basis that EPA had failed to adequately support its "public interest" finding for the registration. The Appeals Court ruling in two consolidated cases, *Natural Resources Defense Council v. U.S. EPA*, No. 15-72308, and *Center for Food Safety v. U.S. EPA*, No. 15-72312, apparently marks the first time that a conditional pesticide registration has been invalidated because a court deemed the public interest finding which is requisite for this type of conditional registration to be inadequately supported. Anti-pesticides activists may be emboldened by this decision to bring future challenges to conditional registrations based on public interest findings.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to issue "conditional" registrations under specified circumstances. One circumstance under which EPA can issue a conditional registration is if the applicant has not submitted a complete dossier of data and information supporting a registration application. EPA may conditionally register a pesticide for a period of time "reasonably sufficient" to allow for the generation and submission of required data, if such data were not initially submitted as part of the application "because a period reasonably sufficient for generation of the data ha[d] not elapsed since [EPA] first imposed the data requirement." Such a conditional registration is known as a 3(c)(7)(C) registration because it is issued under Section 3(c)(7)(C) of FIFRA. To issue a 3(c)(7)(C) registration, EPA must find that use of the pesticide for the period of the conditional registration "is in the public

Practice Areas

Environment & Product Regulation

interest.”

In May 2015, EPA registered a pesticide product that contains nanoscale silver as the active ingredient (NSPW). Silver has long been known to have antimicrobial properties, and there are a number of registered pesticide products that contain silver as the active ingredient. There is only one other currently registered nanosilver product. The registration application for NSPW did not contain a complete dossier of information addressing all of the data requirements applicable to this type of registration; therefore, the registration granted for NSPW was a 3(c)(7)(C) conditional registration good for four years (during which time the registrant was to submit all required data and information necessary to support an unconditional registration). In granting the conditional registration for NSPW, EPA concluded that it would be in the public’s interest to do so because NSPW has the potential to reduce the amount of silver entering the environment from pesticidal uses. EPA based this conclusion on the facts that NSPW has a lower application rate and lower mobility coefficient than conventional silver products, and the assumption that current users of conventional silver products will switch to using NSPW, or, alternatively, because NSPW will not be used to provide antimicrobial properties in more products than are currently protected by conventional silver-containing pesticides.

The Ninth Circuit panel found that EPA had met all requirements for granting a 3(c)(7)(C) conditional registration for NSPW, with the exception of the public interest finding. In discussing this requirement, the Court noted that the public interest finding is an important distinction between a conditional registration and an unconditional registration. The requirement that EPA find a conditional registration to be in the public’s interest is an important underpinning of the regulatory approval in instances where a full data set is not available to enable EPA to make an unreserved determination that use of a pesticide will not result in unreasonable adverse effects to the environment.

In analyzing EPA’s NSPW public interest finding, the Court noted that EPA stated that NSPW has the “potential” to reduce the amount of silver entering the environment from pesticidal uses. But EPA did not provide any actual supporting evidence for the conclusion that use of NSPW during the period of the conditional registration would result in less silver entering the environment. EPA’s assumption that current users of conventional silver pesticide products will switch to NSPW-based products did not have any supporting data or evidence, rather it was based on mere speculation. Similarly, EPA’s alternate assumption that NSPW will not be used to provide antimicrobial properties in more products than are currently protected by conventional silver-containing pesticides also was just conjecture. As the Court noted, “EPA cites no evidence in the record to support” either of the assumptions.

In the end, the Court found EPA’s public interest finding for the NSPW conditional registration to be fatally flawed because it was based on EPA’s conclusion that registering NSPW for the conditional registration period would result in less silver entering the environment, but this conclusion was based on the assumption that NSPW “would be used enough by some, but not too much by others, to reduce the amount of silver released into the environment,” and that neither prong of this assumption was anything other than speculation.

The end result of this decision almost certainly will be that EPA and registrants will have to be more diligent in supporting the conclusions that undergird public interest findings for 3(c)(7)(C) conditional registrations. As

noted, this decision is apparently the first time that a conditional registration has been invalidated on the basis of lack of adequate factual support for a public interest finding. The success of the challengers in these cases will likely motivate anti-pesticides activists to examine the public interest findings of future 3(c)(7)(C) conditional registrations to assess whether to challenge individual pesticide registrations.