

## [California Federal Court Rules on the Conditional Registration of Nanosilver-containing Pesticide, Nanosilva](#)

Specifies what is needed for nanomaterial-containing pesticides to meet the public interest requirement for conditional registration under the Federal Insecticide, Fungicide, and Rodenticide Act.

Updated last **January 19, 2018**



### WHAT IT DOES

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[Natural Resources Defense Council v. US Environmental Protection Agency, 857 F.3d 1030 \(9th Cir. 2017\)](#) is a federal case that vacated the conditional registration of NSPW-L30SS – also called Nanosilva, a nanosilver-containing pesticide – under the [Federal Insecticide, Fungicide, and Rodenticide Act](#) (FIFRA).

Prior to this case, the Environmental Protection Agency (EPA) had been promulgating a [policy](#) wherein the EPA regarded each product that incorporated nanosilver as containing a new active ingredient. Pesticides containing new active ingredients qualified for conditional registration under [section 136a\(c\)\(7\)\(C\)](#) and did not require all the risk data that unconditional registration requires so long as the EPA, among other requirements, determines that use of the pesticide is in the public interest. The U.S. Court of Appeals for the Ninth Circuit concluded the EPA had failed to meet the public-interest requirement specified in section 136a(c)(7)(C) when granting a conditional registration to Nanosilva.

Although the EPA asserted Nanosilva registration could potentially fulfill the public-interest requirement, the court held that this potential was insufficient for compliance with 136a(c)(7)(C). According to the court's interpretation of the statute, the public-interest requirement necessitated the EPA to provide substantial evidence prior to conditional registration. Moving forward, the EPA cannot rely on the "potential" for a product to be in the public interest. Furthermore, the EPA cannot depend on post-hoc arguments from historical observations when justifying conditional registrations under 136a(c)(7)(C). The EPA should evaluate information from analogous products when such information is available.

Additionally, the National Resources Defense Council (NRDC) argued that Nanosilva LLC, the manufacturer of Nanosilva, had sufficient time to provide the data necessary for an unconditional registration; however, the court disregarded the time argument as the court decided to vacate the Nanosilva registration prior to addressing the issue.

### BACKGROUND

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FIFRA is federal law established in 1947 and amended in 1972. The Act establishes the guidelines for pesticide examination and registration and is enforced by the EPA. In 2009, a FIFRA Scientific Advisory Panel convened to address the hazards and exposures associated with silver nanoparticles. In its [summary](#), the Panel suggested that the EPA should consider the hazard profiles of silver nanoparticles to be different from the profiles of conventional silver. In 2013, the Court of Appeals for the Ninth Circuit [vacated in part](#) a conditional registration for AGS-20, another silver nanoparticle-containing pesticide. The court held that the EPA erred in its lack of concern regarding health risks associated with AGS-20. The EPA failed to consider risk mitigation, which contravened the

unreasonable adverse effects clause of conditional registration.

#### THE FACTS

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In May of 2015, the EPA granted a [conditional registration](#) to Nanosilva LLC for Nanosilva, a pesticide whose active ingredients were nanoscale silver particles. The EPA granted the conditional registration, finding that doing so was in the public interest and that Nanosilva LLC had insufficient time to generate data required for unconditional registration. In finding that Nanosilva was in the public interest, the EPA reasoned that Nanosilva had the “potential” to reduce the amount of silver released into the environment.

#### PROCEDURAL HISTORY

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On July 27, 2015, the NRDC, as well as the Center for Food Safety (CFS) and International Center for Technology Assessment (ICTA), all of whom had opposed the conditional registration of Nanosilva during public notice and comment, petitioned the U.S. Court of Appeals for the Ninth Circuit to withdraw Nanosilva’s conditional registration status. The Petitioners argued against the EPA’s approval on two claims:

- The EPA failed to support its finding that Nanosilva had insufficient time to meet the data requirements.
- The EPA failed to support its finding that Nanosilva’s conditional registration was in the public interest.

The EPA responded by issuing its [brief](#) on March 8, 2016.

#### DECISION POINTS

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Conditional registration status is acceptable under section 136a(c)(7)(C) of FIFRA ([7 U.S.C. §§ 136-136y](#)), which states:

“The Administrator 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 Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator 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 Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator 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.”

For insight in interpreting this section of FIFRA, the court looked to the legislative history of the statute. The court noted that congressional testimony consistently discussed how conditional registration would be saved for “truly exceptional cases” and that “a more stringent test” would need to be met to meet the public-interest requirement. The court held that Nanosilva’s “potential” to be in the public interest failed to pass this “more stringent test.”

In considering the EPA’s public-interest finding, the court analyzed three premises disputed by the Petitioners that underlie the EPA’s finding that Nanosilva had the potential to reduce the amount of silver released into the environment:

1. Nanosilva’s lower application rate (i.e., it uses less silver)

- The court found that the EPA presented substantial evidence to support its findings regarding Nanosilva’s toxicity profile. In doing so, the court deferred to the EPA for “making predictions, within its area of special expertise, at the frontiers of science.”

2. Nanosilva’s lower mobility rate (i.e., it is less likely to release silver into the environment):

- The court found the EPA'S reliance on an undisputed textile-leaching study, as well as a contested plastic-leaching study, constituted substantial evidence. Nanosilva's stability achieved through attachment to a larger particle and diminished release rate relative to silver salts persuaded the court that Nanosilva retained a lower mobility rate.

3. Current users of conventional, silver-containing pesticides would switch to Nanosilva (the substitution assumption), and/or Nanosilva would not be incorporated into new products to the extent that it would increase the amount of silver released (the no-new-product assumption):

- In analyzing the substitution assumption, the court found the EPA's argument, that market saturation and inelasticity would influence users to substitute conventional silver-containing pesticides with Nanosilva, to be inadequate. The court considered this argument to be a post-hoc rationalization, irrelevant to the silver-containing pesticide market and incapable of supporting the substitution assumption.
- In the absence of factual support, the court concluded that the potential for Nanosilva's incorporation into new products was inconsistent with the EPA's no-new-product assumption. Despite prohibitive costs, the potential for incorporation into new products weighed against public interest, given the unsupported substitution assumption.
- Without evidence in the record to support either assumption, the court posited that Nanosilva could *elevate* the total quantity of silver in the environment. The EPA should have, the court said, used information collected from another silver nanoparticle-containing pesticide, AGS-20, to substantiate the EPA's assumptions. The court had "to imagine that at least some data about the use of AGS-20 and adoption were ascertainable and would have been useful in evaluating the EPA's assumptions."

The void in the EPA's evidence contravened the language of section 136a(c)(7)(C). The closing of section 136a(c)(7)(C) reads, "that use of the pesticide *is* in the public interest." In accordance with the statute, the court interpreted this language to mean that substantial evidence, supporting the public-interest requirement, should have been provided prior to Nanosilva's conditional registration. Data collected during the conditional registration period cannot fulfill the public-interest requirement.

#### RELEVANT SCIENCE

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Nanomaterials are chemical substances that measure between 1-100 nanometers (nm, 10<sup>-9</sup> meters) along at least one dimension. Nanomaterials exhibit chemical and physical characteristics distinct from their bulk material counterparts. Because of their different properties, nanomaterials interact with environmental chemicals to yield new and unclear manifestations. The EPA uses conservative assumptions to derive unique risk profiles and [is constantly refining methods used to assess nanomaterial characteristics](#). The active ingredients in the proprietary Nanosilva formulation are silver nanoparticles. In response to companies seeking to use nanosilver in their pesticides, a scientific advisory panel suggested that the distinct biological distributions of silver nanoparticles could lead to unique hazard profiles.

Silver is an [antimicrobial](#) agent that is becoming increasingly incorporated into [pesticide](#) formulation and materials as a preservative. In relation to their ionic counterparts, silver nanoparticles have greater surface areas to which microorganisms are exposed; the superior surface area improves the chances of microbial death. As a result, the amounts of silver nanoparticles needed for products to be effective (application rates) are lower than conventional ionic silver-containing pesticides. In addition, silver nanoparticles are designed remain chemically stable throughout the product's time of usage. Relevant to the current case, silver nanoparticles are less mobile – that is, they dissolve from the product and transported throughout the environment – than ionic silver.

The Nanosilva formulation enhances product stability by anchoring silver nanoparticles to silica microparticles embedded in a polymer textile. By adding Nanosilva to [polymeric materials](#), unwanted effects from bacterial and fungal growth, such as foul odors, are prevented. The strong bonds formed between the silver nanoparticles and silica microparticles minimize the possibility that Nanosilva leaches and contributes to hazardous silver levels.

#### WHERE & WHEN

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The United States Court of Appeals for the Ninth Circuit delivered its opinion on May 30, 2017.

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**COUNSEL**

The NRDC is represented by Jaclyn H. Prange; and Aaron Colangelo. The EPA is represented by Sue Chen; John C. Cruden, Assistant Attorney General, Environmental Defense Section, Environment & Natural Resources Division, United States Department of Justice; and Amber Aranda, Of Counsel, Office of General Counsel, the EPA.

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**STATUS**

The court vacated Nanosilva's conditional registration on May 30, 2017 and remanded the case. No appeal has been filed at this time.

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**RECOMMENDED CITATION**

Duke SciPol, "Natural Resources Defense Council v. US Environmental Protection Agency" available at <http://scipol.duke.edu/content/california-federal-court-rules-conditional-registration-nanosilver-containing-pesticide> (1/19/2018).

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