FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, *Petitioner*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *Respondent*, HEIQ MATERIALS AG, *Respondent-Intervenor*.	No. 12-70268 OPINION

On Petition for Review of an Order of the
Environmental Protection Agency

Argued and Submitted
January 16, 2013—San Francisco, California

Filed November 7, 2013

Before: Jerome Farris and Jay S. Bybee, Circuit Judges,
and Lynn S. Adelman, District Judge.[*]

Opinion by Judge Bybee;
Partial Concurrence and Partial Dissent by Judge Adelman

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[*] The Honorable Lynn S. Adelman, District Judge for the U.S. District Court for the Eastern District of Wisconsin, sitting by designation.

SUMMARY[**]

Federal Insecticide, Fungicide, and Rodenticide Act

The panel granted in part and denied in part a petition for review of a decision of the Environmental Protection Agency granting an application for conditional registration of two pesticides, AGS-20 and AGS-20 U, that applicant HeiQ Materials sought to apply to manufactured textiles such as clothing, blankets, and carpet.

The Federal Insecticide, Fungicide, and Rodenticide Act prohibits the sale of any pesticide that has not been "registered" with the Environmental Protection Agency. AGS-20 and AGS-29U (collectively, "AGS-20) uses nanosilver to suppress the growth of microbes that cause odors, stains, discoloration, and degradation. The EPA conducted a risk assessment of AGS-20 that was published in its decision granting HeiQ's application for conditional registration.

The panel first held that petitioner Natural Resources Defense Council, Inc. had Article III standing to challenge the EPA's conditional registration of AGS-20. Second, the panel held that substantial evidence supported the EPA's decision to use the characteristics of toddlers rather than infants in determining whether AGS-20 placed consumers at risk. Third, the panel vacated the EPA's decision insofar as it concluded that there was no risk concern requiring mitigation for short- and intermediate-term aggregate oral

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

and dermal exposure to textiles that are surface-coated with AGS-20. Fourth, the panel held that substantial evidence supported the EPA's decision not to consider additional sources of exposure to nanosilver other than AGS-20 in concluding that the product would not have adverse effects on consumers.

District Judge Adelman concurred in the judgment insofar as it granted the petition in part and remanded to the EPA, and dissented from the judgment insofar as it denies the petition in part. Judge Adelman would grant the petition for review in full.

COUNSEL

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OPINION

BYBEE, Circuit Judge:

The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") prohibits the sale of any pesticide that has not been "registered" with the Environmental Protection Agency ("EPA"). 7 U.S.C. § 136a(a). Through the registration requirement, EPA ensures that no pesticides that will cause "unreasonable adverse effects" on human health or the environment are sold in the United States. *See id.* This case involves EPA's conditional registration of two pesticides, AGS-20 and AGS-20 U (collectively "AGS-20"), that applicant-intervenor HeiQ Materials AG seeks to apply to manufactured textiles such as clothing, blankets, and carpet. AGS-20 uses nanosilver—that is, extremely small particles of silver—to suppress the growth of microbes that cause odors, stains, discoloration, and degradation. After receiving comments from the public, EPA conducted a risk assessment of AGS-20 that it published in its decision document, where it granted HeiQ's application for conditional registration. Natural Resources Defense Council, Inc. ("NRDC") petitions us to vacate EPA's decision to conditionally register AGS-20. We have jurisdiction under 7 U.S.C. § 136n(b).

This case presents four issues. First, we must determine whether NRDC has Article III standing. We hold that it does. Second, NRDC contends that EPA erred in deciding not to

use the body weight and other characteristics of infants in determining whether AGS-20 places consumers at risk. In its risk assessment, EPA used the characteristics of a three-year-old toddler rather than an infant because it concluded that toddlers are the subpopulation that is most vulnerable to exposure to AGS-20. We deny NRDC's petition with respect to this claim because EPA's decision is supported by substantial evidence. Third, EPA's risk assessment sets out a rule whereby there is a risk concern requiring mitigation if the "margin of exposure" to AGS-20 in the short- or intermediate-term is less than *or equal to* 1,000. EPA analyzed the possible level of exposure to AGS-20 under a number of different circumstances. One of the scenarios involves a consumer who experiences both dermal and oral contact with AGS-20 applied to a textile as a surface coating. In this single scenario, EPA calculated a "margin of exposure" of 1,000. Based on EPA's own rule, this finding presents a risk concern. We vacate EPA's decision insofar as it concludes that there is no risk concern requiring mitigation for short- and intermediate-term aggregate oral and dermal exposure to textiles that are surface coated with AGS-20. Fourth, NRDC faults EPA for deciding not to consider additional sources of exposure to nanosilver other than AGS-20 in concluding that the product will not have unreasonable adverse effects on consumers. We deny NRDC's petition on this point because EPA's decision is supported by substantial evidence.

I

FIFRA permits EPA to conditionally register a pesticide like AGS-20 that contains a new active ingredient until the agency receives sufficient data from an applicant such as HeiQ to decide whether to issue an unconditional

registration.[1] *See* 7 U.S.C. § 136a(c)(7)(C). Under FIFRA's conditional registration provision:

> 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.

Id. In this case, NRDC contends that EPA erred in determining that "use of the pesticide . . . will not cause any unreasonable adverse effect on the environment" while HeiQ

[1] EPA requested that HeiQ classify AGS-20 as a pesticide with a "new active ingredient" in its application after it consulted with the FIFRA Scientific Advisory Panel and concluded that "the nanosilver active ingredient in AGS-20 differed from the active ingredients in currently registered silver-based antimicrobial products."

collects the data requested by EPA. *Id.* Notably, the phrase "unreasonable adverse effects on the environment" includes "any unreasonable risk *to man or the environment*, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb) (emphasis added).

Pursuant to this statutory framework, EPA conditionally registered AGS-20. The product is an antimicrobial powder that includes nanosilver particles measuring between one and ten nanometers in diameter.[2] The particles slowly release silver ions that suppress the growth of bacteria that cause odors, stains, and similar damage to textiles such as clothing. AGS-20 can either be incorporated into textile fibers prior to the textile manufacturing process or applied as a surface coating to finished textiles.

Before conditionally registering AGS-20, EPA assessed the risks that the product might pose to workers who apply it to textiles, consumers who use goods treated with AGS-20, and the environment. NRDC's challenges focus on the effects on consumers. EPA's assessment assumes that the consumer is a three-year old because it deemed toddlers to be the subpopulation that is *most vulnerable* to the possible harmful effects of the product. Among other things, EPA examined a hypothetical toddler's potential (1) dermal, (2) oral, and (3) aggregate dermal and oral exposure to AGS-20. The measure of aggregate exposure analyzed the possible effects of AGS-20 on a three-year old who was both wearing and mouthing (*i.e.*, chewing or sucking on) clothing or

[2] As a point of reference, a sheet of paper is approximately 100,000 nanometers thick. *Size of the Nanoscale*, Nano.gov, http://www.nano.gov/nanotech-101/what/nano-size (last visited Sept. 23, 2013).

another item treated with AGS-20. The resolution of this case turns on the assumptions used and the calculations performed by EPA in determining that the aggregate exposure measure does not indicate that AGS-20 poses an unreasonable risk to consumers.

II

EPA's conditional registration of AGS-20 "shall be sustained if it is supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). "Substantial evidence means more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Vasquez v. Astrue*, 572 F.3d 586, 591 (9th Cir. 2008) (quoting *Andrews v. Shalala*, 53 F.3d 1035, 1039 (9th Cir. 1995)) (internal quotation marks omitted). "Under the substantial evidence standard, we must affirm the Administrator's finding 'where there is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion" even if it is possible to draw two inconsistent conclusions from the evidence.'" *Nw. Food Processors Ass'n v. Reilly*, 886 F.2d 1075, 1079–80 (9th Cir. 1989) (quoting *St. Elizabeth Cmty. Hosp. v. Heckler*, 745 F.2d 587, 592 (9th Cir. 1984)). When, as in this case, the agency "is making predictions, within its area of special expertise, at the frontiers of science . . . a reviewing court must generally be at its most deferential." *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983).

Although we must give due deference to EPA's findings, "It is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto.*

Ins. Co., 463 U.S. 29, 50 (1983) (citations omitted); *see also Safe Air for Everyone v. EPA*, 488 F.3d 1088, 1091 (9th Cir. 2007) ("[O]ur review of an administrative agency's decision begins and ends with the reasoning that the agency relied upon in making that decision.").

III

As a threshold matter, we hold that NRDC has standing to challenge the EPA's conditional registration of AGS-20. In order to satisfy Article III's standing requirements, a petitioner must demonstrate that "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000) (citation omitted).

EPA argues that NRDC's members do not face an injury that is "actual or imminent" as opposed to "conjectural or hypothetical." EPA's decision to conditionally register AGS-20 increases the threat of future harm to NRDC's members. Absent EPA's authorization, there is roughly no chance that the children of NRDC members will be exposed to AGS-20. Conditional registration of the product increases the odds of exposure. As with many Article III standing cases, the threatened harm "is by nature probabilistic." *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 948 (9th Cir. 2002) (internal quotation and citation omitted). Our goal in these cases is to ensure that the concept of "actual or imminent" harm is not "stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for

Article III purposes." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 n.2 (1992). We have consistently held that an injury is "actual or imminent" where there is a "credible threat" that a probabilistic harm will materialize. *See Covington v. Jefferson Cnty.*, 358 F.3d 626, 641 (9th Cir. 2004) ("A credible threat of risks to [plaintiffs'] home yields a loss of enjoyment of property. That is enough for injury in fact. . . ."); *Cent. Delta Water Agency*, 306 F.3d at 950 ("[W]e agree with those circuits that have recognized that a credible threat of harm is sufficient to constitute actual injury for standing purposes. . . ."); *Hall v. Norton*, 266 F.3d 969, 976 (9th Cir. 2001) ("[E]vidence of a credible threat to the plaintiff's physical well-being from airborne pollutants falls well within the range of injuries to cognizable interests that may confer standing.").

NRDC has carried its burden to demonstrate that there is a "credible threat" that its members' children will be exposed to AGS-20 as a consequence of the EPA's decision to conditionally register the product. The ubiquity of textiles and the lack of public information concerning the chemical treatments applied to them during the manufacturing process would combine to make it nearly impossible for NRDC members to eliminate AGS-20-treated textiles from their children's lives, particularly in light of the expansive scope of permissible applications of AGS-20 acknowledged by EPA. NRDC's members cannot reasonably assure that the carpets at the daycare center, the jackets worn by a caretaker, or the seats on the school bus have not been treated with AGS-20.

The potentially extensive applications of AGS-20 and the inability of NRDC's members to fully control their children's exposure to the product distinguish this case from the two cases relied on most heavily by EPA: *City of Los Angeles v.*

Lyons, 461 U.S. 95 (1983), and *Coalition for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275 (D.C. Cir. 2012). In *Lyons*, the probability that the plaintiff would be exposed to the risk of harm at issue was low because he was unlikely to have another encounter with a member of the Los Angeles Police Department that would lead to an officer administering an allegedly injurious chokehold. *Lyons*, 461 U.S. at 105–06. The contingency in this case—whether the children of NRDC members will sustain dermal and oral contact with AGS-20-treated textiles—is far more likely to materialize given the wide range of proposed uses of the product. In *Coalition for Mercury-Free Drugs*, the plaintiffs asked the Food and Drug Administration ("FDA") to ban the use of thimerosal—a mercury-based preservative—in vaccines. *Coal. for Mercury-Free Drugs*, 671 F.3d at 1276–77. FDA denied the plaintiffs' petition, and they filed suit in district court. *Id.* at 1277. The district court dismissed the suit because the plaintiffs lacked standing, and the court of appeals affirmed. *Id*. The plaintiffs themselves did not intend to receive vaccines with thimerosal, which is a realistic objective because mercury-free versions of all essential vaccines are readily available. *Id.* at 1280. Thus, the plaintiffs could not show "that they face a 'certainly impending,' or even likely, risk of future physical injury from thimerosal in vaccines." *Id*. By contrast, it is far more difficult for parents to ensure that their children are not exposed to textiles treated with a particular coating than to verify the type of vaccines that their children receive. Exposure to common textiles is a far greater risk for the public than exposure to particular vaccines. In short, this case differs from *Lyons* because the probability of exposure to the risk of harm is quite high, and it differs from *Coalition for Mercury-Free Drugs* because the probability that NRDC's members will be able to avoid exposing their children to the risk of harm is quite low.

We conclude that NRDC has shown a "credible threat" that its members' children will be exposed to AGS-20, meaning that the purported injury is "actual or imminent." Neither Supreme Court precedent nor the out-of-circuit cases relied on by EPA dictate that we hold otherwise. NRDC has standing to sue under Article III and so we must proceed to consider the merits of its petition.

IV

A. *EPA's Decision to Use the Characteristics of Toddlers Rather Than Infants in its Risk Assessment of AGS-20*

We begin with NRDC's challenge to EPA's decision to use the characteristics of three-year olds rather than infants in its risk assessment on the grounds that they are the subpopulation that is most vulnerable to AGS-20 exposure.[3]

[3] NRDC did not forfeit its argument that EPA should have analyzed the effects of AGS-20 on infants. In its comments to EPA, NRDC indicated its position that the EPA must analyze both toddlers and infants. Its September 10, 2010 comment states that "some mouthing of the material is highly likely to occur with infants and young children who come into contact with the clothing. . . . The special considerations of the impact of these exposures on children and infants must be incorporated into EPA's assessment of these unique materials." NRDC's reference to infants—as distinct from older children—was sufficient to notify EPA of the possible need to consider the effects of AGS-20 on infants. *See Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010) ("[A] claimant need not raise an issue using precise legal formulations, as long as enough clarity is provided that the decision maker understands the issue raised."); *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1024 (9th Cir. 2007) ("[W]e will not invoke the waiver rule in our review of a notice-and-comment proceeding if an agency has had an opportunity to consider the issue."). NRDC's admittedly brief reference to the fact that mouthing of material is especially likely to occur with infants—and not just young children—also "show[ed] why the mistake was of possible

We hold that EPA's decision is supported by substantial evidence.

As part of its risk assessment, EPA must determine which subpopulation is most vulnerable to the pesticide at issue. If the pesticide does not pose risk concerns for the most vulnerable subpopulation, then it is presumably safe for less vulnerable groups as well. Here, EPA used the body weight of an average three-year old in calculating the dermal and oral exposure to AGS-20 of a child who wears and mouths clothing treated with the product. NRDC asserts that EPA should have used the body weight of an infant. EPA's decision to use the weight of a three-year old—thereby implying that toddlers rather than infants are the most vulnerable subpopulation—is supported by substantial evidence because it is consistent with EPA's practices and the specific behaviors most likely to cause exposure to AGS-20.

The agency's guidelines state that past assessments of the effects of dermal and non-dietary oral exposure to a pesticide have found that toddlers between three and five years old are the most vulnerable subpopulation. By using the body weight of an average three-year old, the agency selected the lightest—and hence most vulnerable—member of the subpopulation specified in its guidelines. This is wholly consistent with the agency's general approach: it routinely uses the body weight of three-year olds to evaluate the risk of dermal and oral exposure to pesticides such as AGS-20 that are applied to textiles.

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significance in the results." *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978) (internal quotation marks and citations omitted).

In evaluating the specific risks posed by AGS-20, EPA cited a study that considered the extent to which surface-treated textiles shed small particulates when laundered. The study provided a useful baseline for EPA's analysis of whether nanosilver ions might be released when a child chews on a textile that has been surface-treated with AGS-20. The agency explained that while the study "does not exactly simulate wearing or chewing on textiles, because it involved aggressive conditions potentially resulting in greater release than might otherwise occur during chewing on or wearing textiles, it does provide a reasonable first estimate for the amount [of] silver transferred to the mouth while chewing on and transferred to skin while wearing textiles treated with AGS-20." Importantly, EPA observed that "aggressive conditions" potentially cause the release of more nanosilver ions. From this, it is reasonable to conclude that aggressively chewing on clothing treated with AGS-20—as a three-year old might—causes more exposure than sucking on or mouthing the same textile—as an infant would be inclined to do.

EPA's decision to use the characteristics of three-year olds rather than infants in its risk assessment created tradeoffs in the elements that comprise the formula that the agency used to calculate oral and dermal exposure to AGS-20. Infants are more vulnerable because they weigh less, but toddlers are more vulnerable because they can chew fabric aggressively. Infants spend more time resting on a single piece of cloth, such as a parent's shirt, but toddlers move around and make contact with more textiles. NRDC has merely demonstrated that there is a reasonable basis for disagreement over whether infants are a somewhat more vulnerable subpopulation than toddlers. Under these circumstances, the agency's findings are "supported by

substantial evidence when considered on the record as a whole," and we deny the petition.[4] 7 U.S.C. § 136n(b); *see Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 522–23 (1981) ("[W]e have defined substantial evidence as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. The reviewing court must take into account contradictory evidence in the record, but the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.") (internal quotations and citations omitted); *Envtl. Def. Ctr. Inc. v. EPA*, 344 F.3d 832, 872 n.56 (9th Cir. 2003); *Nw. Food Processors Ass'n*, 886 F.2d at 1079–80; *ASARCO, Inc. v. OSHA*, 746 F.2d 483, 490 (9th Cir. 1984) ("Where the agency presents scientifically respectable evidence which the petitioner can continually dispute with rival, and we will assume, equally respectable evidence, the court must not second-guess the particular way the agency chooses to weigh the conflicting evidence or resolve the dispute.") (internal quotations and citation omitted).

[4] NRDC argues that observations about how toddlers can chew more aggressively and cover more of the surface area of a textile because they have larger mouths, more teeth, and stronger jaws are post hoc rationalizations that lack support in the record. To the contrary, they are commonsense statements about the apparent distinctions between children of different ages. NRDC relies on the same type of commonsense observations. *See Petitioner's Opening Br.* at 26 ("It is common sense that infants and babies are held by parents and caretakers more often than other children, giving them more frequent access to shoulders and sleeves, and that teething infants (not toddlers) are most likely to chew on clothing and other fabrics within reach."). The agency need not state every patently obvious observation underlying its reasoning.

B. *EPA's Conclusion That Toddlers' Potential Aggregate Dermal and Oral Exposure to AGS-20 Applied as a Surface Treatment Does Not Pose a Risk Concern Requiring Mitigation*

Next, we address whether EPA's determination that there is no risk concern for toddlers exposed to AGS-20-treated textiles is supported by substantial evidence. EPA's own rule of decision states that there is a risk concern if the aggregate dermal and oral exposure to AGS-20 is less than *or equal to* 1,000. In one instance, EPA calculated an aggregate exposure of 1,000, which is obviously equal to 1,000. Yet EPA erroneously concluded that there was no risk concern on the basis that all of its calculations exceeded 1,000.[5] We vacate this portion of EPA's decision and remand to the agency because it did not satisfy its own rule for determining when there is a risk concern requiring mitigation.

Central to EPA's analysis of the risks posed by a pesticide is its calculation of the margin of exposure ("MOE"), which is used to determine whether exposure to a pesticide might cause an adverse effect. To discern whether a risk concern exists, EPA first calculates a target MOE by multiplying a variety of uncertainty factors. Here, EPA calculated a target MOE of 1,000 for short-term (less than 30 days) and

[5] NRDC did not raise this issue in its opening brief. The court raised it *sua sponte* and the parties submitted supplemental briefing on the question at our request.

intermediate-term (between one and six months) exposure to AGS-20.[6]

After setting the target MOE, the agency calculated the actual (or "calculated") MOE under a number of scenarios. The actual MOE equals the toxicological point of departure divided by the daily dose. The point of departure is the amount of the pesticide that a person must be exposed to before there is a possible adverse effect. Here, EPA used 0.5 mg/kg/day as the point of departure for both dermal and oral exposure to AGS-20. This figure was based on a prior study that found no adverse effects in mice who had ingested 0.5 mg/kg/day of nanosilver for 28 days.[7] The daily dose is the amount of nanosilver that a person might be exposed to under various scenarios, such as wearing a shirt treated with AGS-20 or chewing on a blanket coated with the product.

All else equal, a higher actual MOE means there is less cause for concern. For example, if studies showed that humans exposed to 500 units per day of a particular pesticide experienced no adverse health effects, we would likely tolerate being exposed to 50 units of the pesticide per day. In this hypothetical, the actual MOE would be 10 (500 / 50 =

[6] The short- and intermediate-term MOEs were calculated using a ten-fold interspecies uncertainty factor to account for the fact that the data was derived from experiments on animals rather than humans, a ten-fold intraspecies uncertainty factor to account for variable sensitivity to pesticides among different humans, and a ten-fold database uncertainty factor to account for the incomplete data on nanosilver toxicity. The three uncertainty factors of ten are multiplied to produce the target MOE of 1,000 (10 x 10 x 10 = 1,000).

[7] The risk that nanosilver might affect humans differently than mice is accounted for by the ten-fold interspecies uncertainty factor.

10). But we would presumably be even more comfortable if we were exposed to only 5 units of the pesticide per day, in which case the actual MOE would be 100 (500 / 5 = 100). In reality, the EPA cannot be absolutely certain that it is safe for humans to be exposed to, say, 500 units per day of the pesticide where, as here, the product is new and has not been extensively studied. For this reason, the actual MOE must exceed the target MOE, which, as noted, accounts for various uncertainty factors.

The EPA's decision document offers the following rule of decision for determining whether there is a risk concern:

- If calculated MOE > target MOE: risk is not of concern and mitigation is not required

- If calculated MOE ≤ target MOE: risk is of concern and mitigation is required

In Table 4 of the Decision Document, the EPA lists the target MOE's for AGS-20 based on the interspecies, intraspecies, and database uncertainty factors that it identified:

Table 4 — Target Margins of Exposure

Continuous and Daily Exposure Duration	Target MOE		
	Inhalation	Oral	Dermal
Short-Term (< 30 days)	1,000	1,000	1,000
Intermediate-Term (1 to 6 months)	1,000	1,000	1,000
Long-Term (> 6 months)	3,000	3,000	3,000

There is no risk concern if the actual MOE via inhalation, oral, or dermal exposure is greater than 1,000 for short- or intermediate-term exposure, or greater than 3,000 for long-term exposure. If, on the other hand, the calculated MOE is less than or equal to 1,000 for short-term or intermediate-term exposure, or less than or equal to 3,000 for long-term exposure, there is a risk concern and mitigation is required.

In order to determine the potential risks posed by AGS-20 to consumers, EPA evaluated the actual MOE for inhalation, dermal contact (*i.e.*, wearing a shirt treated with AGS-20), and oral contact (*i.e.*, chewing on a blanket treated with AGS-20).[8] EPA also computed the actual MOE for "aggregate"

[8] In calculating the dermal and oral MOE, EPA assumed that the textile contains 20 parts per million of nanosilver applied as a surface coating, which is the maximum amount permitted by EPA. AGS-20 can also be incorporated into textile fibers, and EPA conducted the same analysis of both incorporated and surface-coated textiles. But only the surface-coated treatment type is subject to the issue raised here because the actual MOE

dermal and oral contact, which estimates the exposure faced by a toddler who, for example, chews on an AGS-20-treated shirt while wearing the shirt. Table 12 of the decision document, which is excerpted in part below, shows the actual aggregate MOE.

Table 12 (excerpt)

Application Rate (mg/kg) Treatment Type	Incidental Oral Dose (mg/kg/ day)	Dermal Dose (mg/kg/ day)	Aggregate Dose (mg/kg/ day)	Aggregate MOE
20 Surface Coated	0.00020	0.000011	0.00021	2,400
	0.00047	0.000027	0.00050	1,000
100 Incorporated in Fibers	0.00010	0.000057	0.00016	3,100
	0.000087	0.000049	0.00014	3,600

The notable finding is that the aggregate MOE for a surface-coated textile is 1,000. Under the EPA's own rule of decision, there is a risk concern requiring mitigation when the short- or intermediate-term MOE is less than *or equal to* 1,000. EPA seemingly overlooked its rule in describing its findings. The agency wrote that "[a]ll of these MOE's are greater than the target MOE of 1,000 indicating that the risk for short- and intermediate-term exposure to toddlers who wear and chew on AGS-20 treated textiles is not of concern." One page later, EPA noted that "[a]ggregating the dermal and oral daily doses for children yielded MOEs ranging from

for the incorporated treatment type was consistently higher (*i.e.*, less likely to pose risk of an adverse effect).

1,000 to 3,600, which is not of concern because they exceed the target MOE of 1,000." These statements are not supported by substantial evidence because a calculated MOE of 1,000 poses a risk concern given that it is less than *or equal to* the target MOE of 1,000.

In supplemental briefing addressing this issue, EPA raises two arguments. First, EPA contends that the precise aggregate MOE is 1,006, not 1,000. As noted above, the MOE is the point of departure divided by the daily dose, and EPA used 0.5 mg/kg/day as the point of departure. As Table 12 indicates, the aggregate daily dose is the sum of the oral dose and the dermal dose. In the relevant line of Table 12, the oral dose is 0.00047 and the dermal dose is 0.000027. These two figures are summed for an aggregate dose of 0.00050. The point of departure (0.5 mg/kg/day) is then divided by this aggregate daily dose (0.00050 mg/kg/day) to produce the aggregate MOE (1,000).

But EPA points out that 0.00047 + 0.000027 is not actually 0.00050; rather it is 0.000497. If we use 0.000497 as the aggregate daily dose, then the aggregate MOE is 1,006 because 0.5 / 0.000497 = 1,006. Since 1,006 is greater than 1,000, EPA argues there is no risk concern.

There is a good reason, however, why EPA used 0.00050 as the aggregate daily dose in Table 12 instead of 0.000497. In several places throughout the decision document, EPA noted that it was rounding the daily dose to two significant digits. In footnotes accompanying both Table 10, which provides the oral daily dose, and Table 11, which provides the dermal daily dose, EPA stated that the numbers were rounded to two significant digits. The oral and dermal daily doses

reprinted in Table 12—which is at issue here—are therefore rounded to two significant digits as well.

Importantly, the oral dose (0.00047) has five digits after the decimal point and the dermal dose (0.000027) has six digits after the decimal point. The sum of these two numbers—which is the aggregate daily dose—can have no more than five digits after the decimal point because of the rule that "[w]hen measured quantities are added or subtracted, the number of decimal places in the result is the same as that in the quantity with the greatest uncertainty and hence the smallest number of decimal places." William L. Masterton, Cecile N. Hurley & Edward J. Neth, *Chemistry: Principles and Reactions* 12 (7th ed. 2012) (emphasis removed). In Table 12, EPA correctly offered an aggregate daily dose with five digits after the decimal point (0.00050). EPA's data is not precise enough to allow it to "unround" this number to 0.000497, as it attempts to do in its supplemental brief. The data available in the decision document only permit us to conclude that the aggregate dose is 0.00050, which means that the aggregate MOE is 1,000, and not 1,006.

EPA's second argument is that its MOE calculations are based on very conservative assumptions so an actual MOE in the neighborhood of 1,000 does not mean that consumers are at risk. For example, using a target MOE of 1,000 means that a toddler simultaneously wearing and chewing a textile treated with AGS-20 can be exposed to no more than 1/1000th of the amount of nanosilver that has been shown to produce no harmful effects in mice in laboratory studies. Although EPA's point is well taken as a practical matter, it is irrelevant as a legal matter. This is EPA's rule, not ours. EPA articulated the assumptions that led it to set the target MOE at 1,000. And it stated the rule that there is a risk

concern if the MOE is less than *or equal to* 1,000. Its assessment then produced an aggregate MOE of 1,000, which means, by its own assumptions, that there is a risk concern requiring mitigation. Having established a rule of decision of less than *or equal to* 1,000, EPA cannot unmake it because its actual MOE is in the neighborhood. Nor can we revise EPA's assumptions, alter its rule of decision, or perform our own risk assessment. *See State Farm*, 463 U.S. at 50 ("It is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." (citations omitted)); *Safe Air for Everyone*, 488 F.3d at 1091 ("[O]ur review of an administrative agency's decision begins and ends with the reasoning that the agency relied upon in making that decision."). EPA may wish to revisit its standards in the future, but it cannot ignore them.

EPA's conclusion that short- and intermediate- term aggregate dermal and oral exposure to textiles surface-coated with AGS-20 poses no risk concern is not supported by substantial evidence. We grant the petition and vacate EPA's decision to the extent that it states otherwise.

C. *EPA's Decision Not to Account for Potential Sources of Exposure to Nanosilver Other Than AGS-20*

Finally, NRDC takes issue with EPA's decision against conducting an aggregate risk assessment that accounts for sources of potential exposure to nanosilver other than AGS-20. Both parties agree that nanosilver presently exists in other products. EPA explains in its decision document and its brief that there is no data available about whether other nanosilver in the marketplace is chemically similar to AGS-20 or how consumers might be exposed to other sources of nanosilver. NRDC does not dispute this finding, but insists

that it is unreasonable for EPA to effectively assume that consumers will never be exposed to nanosilver that is chemically similar to AGS-20.

As an initial matter, EPA is not obligated by statute to conduct an aggregate risk assessment in conditionally registering a non-food-use pesticide such as AGS-20. In 1996, Congress amended the Federal Food, Drug, and Cosmetic Act to require EPA to complete an aggregate risk assessment for pesticides found in foods. *See* 21 U.S.C. § 346a(b)(2)(A)(ii) (providing that EPA must "determine[] that there is a reasonable certainty that no harm will result from *aggregate exposure* to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information") (emphasis added); *see also* 21 U.S.C. § 346a(b)(1)(A) (stating that the section applies to "a pesticide chemical residue in or on a food."). At the same time, Congress amended FIFRA to require EPA to assess "human dietary risk from residues that result from a *use of a pesticide in or on any food* inconsistent with the standard under" the Federal Food, Drug, and Cosmetic Act. 7 U.S.C. § 136(bb) (emphasis added). In short, Congress expressly required aggregate risk assessment for food-use pesticides, but did not impose a similar requirement on non-food-use pesticides such as AGS-20.

EPA's decision not to conduct an aggregate risk assessment in this instance is consistent with its regulations. "The Agency has discretion to review applications under either the unconditional registration criteria of FIFRA sec. 3(c)(5) or the conditional registration criteria of FIFRA sec. 3(c)(7)." 40 C.F.R. § 152.111. The regulation further provides that "[t]he type of review chosen depends primarily on the extent to which the relevant data base has been

reviewed for completeness and scientific validity. EPA conducts data reviews needed to support unconditional registrations on a chemical-by-chemical basis, according to an established priority list." *Id.* An aggregate risk assessment is thus potentially part of the *unconditional* registration process, which proceeds on a "chemical-by-chemical basis" that might sweep in all types of nanosilver, rather than only AGS-20. But in considering whether to proceed first with conditional registration—which, as noted above, does not require an aggregate risk assessment—EPA considers the completeness of the available data. Here, there is no data whatsoever on whether other types of nanosilver are chemically similar to AGS-20. In urging EPA to conduct an aggregate risk assessment, NRDC is effectively attempting to short circuit the statutory scheme providing for conditional registration by forcing AGS-20 into the unconditional registration process where EPA proceeds on a "chemical-by-chemical basis." It is true that EPA might conduct a full data review sufficient to support an unconditional registration where, as here, it receives "applications for registration of a new active ingredient." *Id.* But unconditional registration is not required, as FIFRA expressly provides that EPA "may conditionally register a pesticide containing *an active ingredient not contained in any currently registered pesticide.*" 7 U.S.C. § 136a(c)(7)(C) (emphasis added).

Within the confines of EPA's conditional review of AGS-20, its decision not to conduct an aggregate risk assessment covering other sources of nanosilver exposure is supported by substantial evidence. As previously noted, after consulting with the FIFRA Scientific Advisory Panel, EPA requested that HeiQ classify its application as a "new active ingredient" application because it "determined that the nanosilver active ingredient in AGS-20 differed from the active ingredients in

currently registered silver-based antimicrobial products." The Scientific Advisory Panel also "cautioned about extrapolating from one nanosilver formulation to another when assessing hazards because differences in particle formulation (e.g., coating and inert ingredients) are likely to affect biological activity, among other things." In light of these perceived differences between types of nanosilver, the Panel "recommended a case-by-case basis approach to hazard and exposure assessment (i.e., product-by-product)."

The Scientific Advisory Panel's statements are meaningful in the absence of any data indicating that other nanosilver is chemically similar to AGS-20. EPA could have blindly speculated that (1) other types of nanosilver are chemically similar to AGS-20 and (2) consumers might be exposed to them in the same way that they are potentially exposed to AGS-20 (e.g., through simultaneous dermal and oral contact). But this possibility does not mean that it was improper for EPA to instead assume that (1) other types of nanosilver might not be chemically similar to AGS-20 in light of the Scientific Advisory Panel's statements or (2) consumers are unlikely to be exposed to them in the same way in meaningful quantities.[9] This is yet another scenario where there is "the possibility of drawing two inconsistent conclusions from the evidence[, which] does not prevent an

[9] It is worth noting that the only calculated MOEs that are particularly close to the target MOEs involve short- and intermediate-term oral and aggregate oral and dermal contact with surface-coated textiles. All of the other calculated MOEs are at least three times greater than the target MOE, meaning it is even less likely that consumers will be exposed to risk from contact with AGS-20 alone or in conjunction with chemically similar nanosilver, if such products even exist. Exposure via dermal contact alone, or simultaneous oral and dermal contact with AGS-20 incorporated into fibers, does not even approach the level where there is a risk concern.

administrative agency's finding from being supported by substantial evidence." *Am. Textile Mfrs. Inst.*, 452 U.S. at 523; *see also Nw. Food Processors Ass'n*, 886 F.2d at 1079–80. We deny the portion of NRDC's petition that faults EPA for deciding not to account for sources of nanosilver other than AGS-20 in conducting its risk assessment.

V

We have considered three distinct issues with EPA's decision to conditionally register AGS-20. First, we deny NRDC's petition with respect to its claim that EPA should have used the body weight and other characteristics of infants in assessing the risks posed to consumers by AGS-20. EPA's decision to consider three-year-old toddlers rather than infants the most vulnerable subpopulation is supported by substantial evidence. Second, we grant the petition and vacate EPA's decision to the extent that it concludes that there is no risk concern requiring mitigation for short- and intermediate-term aggregate oral and dermal exposure to textiles that are surface coated with AGS-20. Our decision to grant the petition and vacate the decision in part is 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. This holding does not affect any portion of EPA's decision where the calculated MOE is greater than 1,000.[10] Third, we deny NRDC's petition with

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[10] The dissent would hold that we need not reach the two arguments raised by NRDC once we conclude that one of EPA's findings is not supported by substantial evidence. *See* Dissent at 29–32. But our decision to evaluate all of NRDC's contentions is consistent with the statute and our case law.

The statute that vests this court with jurisdiction provides that "the court shall have exclusive jurisdiction to affirm or set aside the order complained of *in whole or in part*." 7 U.S.C. § 136n(b) (emphasis added). The dissent's suggestion—that we should remand without resolving the issues that brought the parties before this court so that they may potentially relitigate them in future proceedings—is at odds with the statute. *Cf. Envtl. Def. Fund, Inc. v. EPA*, 485 F.2d 780, 783 (D.C. Cir. 1973) ("FIFRA provides '[u]pon the filing of [a] petition the court [of appeals] shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part.' When the Congress required that courts of appeals exercise exclusive jurisdiction over petitions to review a FIFRA order, it was to ensure speedy resolution of the validity of EPA determinations. . . . This policy would be defeated if we were to allow the [ ] order to be litigated in several proceedings.") (first three alterations in original) (citations omitted).

In similar contexts, we have resolved all of the arguments presented by the party petitioning for review of the agency's action even after determining that one of the claims is meritorious. *See Hall v. EPA*, 273 F.3d 1146, 1152, 1154–55, 1162–64 (9th Cir. 2001) (rejecting the arguments raised in the petitioner's opening brief after deciding to vacate EPA's decision and remand to the agency for an unrelated reason discussed in supplemental briefing); *Ober v. EPA*, 84 F.3d 304, 308, 311–13, 316 (9th Cir. 1996) (resolving the second and third arguments raised by the petitioner in favor of EPA after determining that the petitioner's first argument was meritorious and justified remanding to the agency for further proceedings). In both of these cases, the court granted in part and denied in part the petition for review. *See Hall*, 273 F.3d 1164; *Ober*, 84 F.3d at 316.

respect to its claim that EPA should have considered sources of potential consumer exposure to nanosilver other than AGS-20. EPA's decision not to conduct an aggregate risk assessment of other possible sources of nanosilver exposure is supported by substantial evidence. Each party shall bear its own costs for this petition for review.

We **GRANT** in part the petition, **DENY** in part the petition, and **REMAND**.

ADELMAN, District Judge, concurring in part and dissenting in part:

I concur in the judgment insofar as it grants the petition in part and remands to the EPA. I agree that the NRDC has

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In the specific context of a registration decision by EPA pursuant to FIFRA, the D.C. Circuit has dispensed with all of the petitioner's non-meritorious arguments even after determining that EPA erred with respect to part of the registration decision. *See Envtl. Def. Fund, Inc. v. EPA*, 548 F.2d 998, 1002, 1011–12 (D.C. Cir. 1976) (overruled on other grounds by *Director, Office of Workers' Comp. Program, Dep't of Labor v. Greenwich Collieries*, 512 U.S. 267 (1994)) (affirming several components of EPA's order to suspended the registration of a pesticide despite concluding that EPA erred by acting arbitrarily when deciding one portion of the order and directing EPA to reconsider that portion on remand); *Envtl. Def. Fund, Inc. v. EPA*, 510 F.2d 1292, 1295–96, 1306 (D.C. Cir. 1975) (same).

This salutary rule is particularly appropriate here where the issue on which we remand was not briefed or argued by the parties, but was raised *sua sponte* by the court. The remaining issues were well briefed by both parties and ripe for review. We can see no reason for delaying ruling on these matters.

standing to challenge the EPA's conditional registration of AGS-20 and join Part III of the majority opinion. I also agree that because the EPA inexplicably stated that all calculated MOEs are greater than the target MOE of 1,000, when in fact the calculated MOE for aggregate dermal and oral contact for toddlers exposed to AGS-20 treated textiles is equal to 1,000, the EPA's order conditionally registering AGS-20 is not supported by substantial evidence. I dissent from the judgment insofar as it purports to deny the petition in part.

First, I think that under the majority's reasoning in Part IV.B of its opinion, the petition must be granted in full. As the majority explains, the EPA's conclusion that aggregate dermal and oral exposure to textiles surface-coated with AGS-20 poses no risk concern is not supported by substantial evidence. That being so, it follows that the EPA has failed to demonstrate that its determination that AGS-20 will not have an unreasonable adverse effect on the environment is supported by substantial evidence. Accordingly, the EPA's conditional registration of AGS-20 cannot stand. 7 U.S.C. § 136(a)(c)(7)(C). Because the only relief requested in the NRDC's petition is setting aside the conditional registration, *see* Pet. at 2, it follows that the NRDC's petition should be granted in full.

It is likely that the majority thinks it appropriate to deny the petition in part because it has ruled against the NRDC on the other issues raised in its briefs. But the other issues raised in the NRDC's briefs are not alternative claims for relief; they are alternative reasons for granting the only relief requested in the petition—vacating the conditional registration of AGS-20. Thus, unless the majority thinks that some part of the conditional registration of AGS-20 has survived its conclusion in Part IV.B, the NRDC's petition

should be granted in full. And if the majority does think that some part of the conditional registration has survived, I would ask it to identify that part. It seems to me that the conditional registration does not contain any "parts" at all—either AGS-20 is conditionally registered or it is not—and that therefore nothing could have survived the majority's conclusion in Part IV.B.

Another way of looking at this is that the majority seems to be affirming part of the EPA's *reasoning* in support of its decision to conditionally register AGS-20 rather than part of the *order* granting conditional registration. But appellate courts review decisions, judgments, orders, and decrees—not opinions, factual findings, reasoning, or explanations. *Weissman v. Quail Lodge, Inc.*, 179 F.3d 1194, 1200 (9th Cir. 1999) (quoting *In re Williams*, 156 F.3d 86, 90 (1st Cir. 1998)); *see also* 7 U.S.C. § 136n(b) (court has jurisdiction to "affirm or set aside the *order* complained of in whole or in part" (emphasis added)). Here, because of the majority's conclusion in Part IV.B, the conditional-registration order should be vacated in full, even if the majority believes that some parts of the EPA's reasoning in support of its decision to issue that order are sound.

I also disagree with the majority's decision to comment on the other issues raised by the NRDC. As noted, those issues are alternative grounds for setting aside the EPA's conditional registration of AGS-20. Because the majority has already concluded in Part IV.B that the conditional registration must be set aside, it is unnecessary to comment on the alternative grounds. The majority likely chooses to address the issues because it believes that doing so will provide guidance for the EPA on remand and prevent relitigation. However, it is not clear to me that the majority's

unnecessarily addressing those issues will serve as guidance or prevent relitigation. Because it was not necessary for the majority to address the issues, its comments on them are dicta, and thus it is questionable whether the majority's resolution of the issues will be binding in a subsequent case. Thus, the NRDC or some other injured party might be entitled to relitigate them. For the same reason, the EPA cannot accept the majority's comments as guidance—the EPA cannot be sure that those comments will be binding in a subsequent case. Moreover, the majority's choosing to comment on the issues might lead to unnecessary further litigation. Even though the NRDC has won its case, it might feel the need to seek further review of the majority's unnecessary comments either in this court or in the Supreme Court. Yet, if the case were simply remanded to the EPA on the basis identified by the majority in Part IV.B, the additional issues raised by the NRDC might be rendered moot: the EPA might decide to deny conditional registration of AGS-20 because of the risk concern to toddlers identified by the majority or because of some new information about AGS-20 that has come to light since the EPA last considered the matter. For these reasons, I think the most prudent course is to simply remand to the agency on the ground stated by the majority in Part IV.B. Should the EPA reissue a conditional-registration order and stand by its current reasoning on the other issues raised by the NRDC, those issues can be addressed at that time.

I also disagree with the majority's resolution of the NRDC's other issues. The first of these involves the EPA's decision to use toddlers rather than infants as the most vulnerable subpopulation. The NRDC contends that this

decision is not supported by substantial evidence.[1] The majority finds that the decision is supported by substantial evidence for two reasons: (1) the EPA has in the past used toddlers as the most vulnerable subpopulation, and (2) toddlers behave in ways that make them more vulnerable to AGS-20 exposure than infants.

It is important to emphasize that the EPA does not explain in the decision document why it decided that toddlers are the most vulnerable subpopulation. The EPA does not say that it made this decision in order to remain consistent with its past practices or because toddlers behave in ways that make them more vulnerable to AGS-20 exposure than infants. The lack of an explanation for this key assumption should be enough to require that the EPA's decision be set aside. As the majority recognizes, Maj. Op. at 8, "[i]t is well-established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983). Here, the EPA has articulated no basis for selecting toddlers as the most vulnerable subpopulation. The basis that the majority adopts is one articulated by the agency's appellate counsel in his briefs. *See* Resp. Answering Br. at 48–51. But the Supreme Court has expressly stated that "the courts may not accept appellate counsel's *post hoc* rationalizations for agency action." *Motor Vehicle Mfrs.*, 463 U.S. at 50.

Moreover, I find it puzzling that the majority thinks that the EPA's decision to select toddlers as the most vulnerable

[1] I agree with the majority that the NRDC did not forfeit the argument that the EPA's decision to use toddlers rather than infants as the most vulnerable subpopulation is not supported by substantial evidence. *See* Maj. Op. at 12 n.3.

subpopulation is supported by substantial evidence, in part, because that decision is "consistent with EPA's practices." Maj. Op. at 13. Why should it matter that the decision is consistent with EPA's practices? Maybe it would matter if the EPA could point to some agency document indicating that the agency had studied the issue and determined that the agency should use toddlers as the most vulnerable subpopulation when assessing the risk associated with pesticide exposure, but the agency has pointed to no such document. Instead, the EPA points to a document indicating that the agency has drafted a standard operating procedure providing that, in pesticide assessments, the effects of dermal and non-dietary oral exposures on toddlers should be considered. But this standard operating procedure does not state that the agency should always select toddlers as the most vulnerable subpopulation in pesticide assessments. Rather, it states that toddlers may be used to represent the one-to-six-year-old age group and that they may be assumed to weigh fifteen kilograms. *See* Standard Operating Procedures (SOPs) for Residential Exposure Assessments at 109 (Dec. 19 1997). There is no analysis in this document supporting the conclusion that the one-to-six-year-old age group should be assumed to be the subpopulation most vulnerable to pesticide exposure. Thus, to the extent the agency has a "practice" of using toddlers as the most vulnerable subpopulation in pesticide assessments, that practice appears to be nothing more than a naked assumption unsupported by substantial evidence.

The other reason the majority cites in upholding the agency's decision is that toddlers are likely to receive more exposure to AGS-20 than infants because toddlers are likely to chew on clothing treated with AGS-20 more aggressively than infants. Maj. Op. at 14. Again, however, the EPA never

states in the decision document that it decided to use toddlers as the most vulnerable subpopulation for this reason. Moreover, as the majority recognizes, certain characteristics of infants might cause them to be more vulnerable than toddlers despite their inability to chew as aggressively: infants spend more time resting on a single piece of cloth than toddlers, and because infants weigh less than toddlers, they are more vulnerable to smaller exposures. Maj. Op. at 14. Thus, there are "tradeoffs" to consider when selecting the most vulnerable subpopulation. Maj. Op. at 14. If the EPA had considered these tradeoffs and concluded that toddlers are more vulnerable than infants, then I would agree with the majority that the EPA's decision was supported by substantial evidence—the EPA would have applied its expertise, to which we must defer. But once again, I must emphasize that the agency did no such thing. It is the majority, not the EPA, that has evaluated the tradeoffs and concluded that toddlers are the most vulnerable subpopulation. Maj. Op. at 14–15.

The remaining issue involves the EPA's decision to ignore potential sources of nanosilver other than AGS-20 when determining whether use of AGS-20 would cause unreasonable adverse effects. The majority upholds this decision for two reasons: (1) the EPA is "not obligated by statute" to conduct an aggregate risk assessment when considering whether to conditionally register a pesticide, Maj. Op. at 24, and (2) the EPA's decision to not conduct an aggregate risk assessment involving sources of nanosilver exposure other than AGS-20 is supported by substantial evidence, Maj. Op. at 25. Here, I must confess that I find the majority's approach confusing. If the EPA is "not obligated by statute" to conduct an aggregate risk assessment, why does the majority also consider whether the EPA's decision to not conduct one was supported by substantial evidence? In any

event, as explained below, I would hold that the EPA is obligated by statute to consider whether the pesticide under review will combine with other similar substances in the environment to cause an unreasonable adverse effect. I would also hold that the EPA's failure to consider the effects of aggregate exposure to AGS-20 and other sources of nanosilver is inexcusable.

The majority's holding that the EPA is not obligated by statute to conduct an aggregate risk assessment involves statutory interpretation. Thus, I examine the statute's plain meaning. *See, e.g.*, *United States v. Flores*, 729 F.3d 910, 914 (9th Cir. 2013) ("The interpretation of a statutory provision must begin with the plain meaning of its language" (internal quotation marks and citation omitted)). FIFRA states that the EPA may conditionally register a pesticide "only if the Administrator determines that use of the pesticide during [the conditional-registration] period will not cause any unreasonable adverse effect on the environment and that use of the pesticide is in the public interest." 7 U.S.C. § 136a(c)(7)(C). The term "unreasonable adverse effect" means, among other things, "any unreasonable risk to man or the environment" 7 U.S.C. § 136(bb). It is plain to me that if use of a pesticide will cause aggregate exposure to a certain substance or family of related substances to reach dangerous levels, then use of that pesticide has the potential to cause an unreasonable risk to man or the environment. Thus, the plain text of the FIFRA requires the EPA to study whether aggregate exposure will result in an unreasonable adverse effect.

The majority reasons that because Congress did not expressly state in the FIFRA that the EPA must consider risks caused by aggregate exposure, like it did in a different statute,

it must have intended for the EPA to ignore that risk when evaluating pesticides for conditional registration. The majority is essentially telling us that Congress would have wanted the EPA to approve the use of a pesticide even if its use could, when combined with uses of other substances, result in unreasonably harmful effects on the environment. I think it is obvious that Congress, in instructing the EPA to approve the use of a pesticide "only if" it determines that such use will not cause any unreasonable adverse effect on the environment, had no such intent.

The majority also reasons that the EPA's decision to ignore the effects of aggregate exposure to nanosilvers was supported by substantial evidence. The majority seems to think that because the EPA did not have sufficient information to form any firm conclusions about the effects of aggregate exposure to AGS-20 and other nanosilvers, it was permitted to ignore the risk that such aggregate exposure could result in unreasonable adverse effects. Maj. Op. at 26–27. I think the majority has things backwards. The FIFRA states that the EPA may conditionally register a pesticide "only if" it first determines that use of the pesticide "will not cause" any unreasonable adverse effect. 7 U.S.C. § 136a(c)(7)(C). It follows from this that if the EPA lacks information to determine whether use of a pesticide will cause an unreasonable adverse effect, then the EPA's only option is to deny conditional registration. The majority's approach would be sound only if the FIFRA stated that the EPA may grant conditional registration "unless" it determines that use of the pesticide "will cause" an unreasonable adverse effect. As the FIFRA does not so state, I would hold that the EPA may not conditionally register a pesticide when it has no

idea whether use of that pesticide will, when aggregated with other substances in the environment, cause unreasonable harm.