REDACTED

No. 20-72794

IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL,

Petitioner,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,

Respondents,

THE HARTZ MOUNTAIN CORPORATION,

Respondent-Intervenor.

On Petition for Review of an Order of the U.S. Environmental Protection Agency

BRIEF OF PETITIONER NATURAL RESOURCES DEFENSE COUNCIL

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CORPORATE DISCLOSURE STATEMENT

Petitioner Natural Resources Defense Council, Inc. (NRDC) is a nonprofit corporation with no parent corporation and no outstanding stock shares or other securities in the hands of the public. NRDC does not have any parent, subsidiary, or affiliate that has issued stock shares or other securities to the public. No publicly held corporation owns any stock in NRDC.

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INTRODUCTION

The pesticide tetrachlorvinphos (TCVP) is highly toxic to young children's developing brains. Such a dangerous pesticide should come nowhere near a toddler. Yet, the Environmental Protection Agency (EPA) continues to allow TCVP to be used inside families' homes, in flea collars for household pets, where children who touch pets wearing the collars get the pesticide on their hands and then, from their hands, in their mouths. EPA's own scientists acknowledge that ingesting even a small amount of TCVP can harm children's brain development, putting them at risk for delayed mental development, attention disorders, autism, and lower IQ scores. But EPA nonetheless refuses to protect children from these products.

In 2009, Natural Resources Defense Council (NRDC) petitioned EPA to fulfill its statutory duty under the Federal Insecticide, Fungicide, and Rodenticide Act and remove TCVP pet collars from the market. (Myriad alternative products, available at similar prices, are just as effective at controlling fleas and ticks but do not endanger children's brain development.) The intervening dozen years have been marked by EPA's "egregious" delay, "broken promises," and repeated trips to this Court. *In re NRDC*, 956 F.3d 1134, 1142–43 (9th Cir. 2020). In 2016, following an earlier remand, EPA found that TCVP collars pose risks of concern to children. In 2020, after this Court issued a writ of mandamus ordering the agency to address those risks, EPA cast that conclusion aside and denied NRDC's petition to ban these products. But EPA's new analysis does not support its change of course.

The primary reason for EPA's baseless reversal is careless math. After initially finding in 2016 that TCVP collars present serious risks to children, EPA refused to take the next step of granting NRDC's petition. Instead, it told this Court that it was missing a critical piece of information: the ratio of liquid TCVP to dust TCVP released by pet collars. (EPA assumes that liquid TCVP clings to pets' fur more stubbornly than dust TCVP and thus is less readily transferred from treated animals onto children's hands.) The manufacturer of TCVP collars, Respondent-Intervenor Hartz Mountain Corporation (Hartz), eventually

then flubbed the calculation of the very number it deemed essential to its risk analysis. Rather than calculating the ratio of the weight of a collar's dust TCVP to its liquid TCVP, as the agency said it intended to do, EPA instead calculated the ratio of dust to everything else in the collar—plastic, inert ingredients, and liquid TCVP. Bad math made the difference: Using the wrong ratio in its analysis led EPA to underestimate TCVP collars' unreasonable risks to children and, ultimately, to deny NRDC's petition.

EPA compounded this error by asserting, for the first time, that all pet owners will trim off 20% of their pets' collars and thereby reduce children's exposure to TCVP. This sweeping assumption reversed EPA's previous, indisputably accurate finding that the agency cannot predict the precise amount of collar that millions of pet owners will cut off each time they fit a collar to their pets' necks. EPA did not substantiate its newfound prescience. In fact, EPA ignored evidence that TCVP

collars *cannot be trimmed* by 20% and still fit around some large dogs' necks. Instead, EPA simply wished away a significant portion of the active ingredient in TCVP pet collars, further distorting its analysis.

These glaring, fundamental deficiencies in EPA's analysis demand vacatur of EPA's petition denial. Further, given the "widespread, serious risks" to children's health and EPA's history of having repeatedly "kicked the can down the road and betrayed its prior assurances of timely action," *In re NRDC*, 956 F.3d at 1136, the Court should order EPA to act expeditiously on remand and revise its response to NRDC's petition within 30 days.

JURISDICTION

EPA's denial of NRDC's petition to cancel the registrations of TCVP's pet uses is a final order reviewable by this Court. 7 U.S.C. §§ 136d(h), 136n(b); see In re NRDC, 956 F.3d at 1138 (stating that the Court "would have jurisdiction to review the EPA's final decision resolving NRDC's petition"). EPA denied NRDC's petition on July 21, 2020. 1-ER-002–43. NRDC timely filed a petition for review in this Court on September 18, 2020, within 60 days of the order's entry. 7 U.S.C. § 136n(b); 40 C.F.R. § 23.6. NRDC was a party to the EPA proceedings, has a place of business in this Circuit, ADD-08¹ (Trujillo Decl. ¶ 3), and is adversely affected by EPA's denial. See 7 U.S.C. § 136n(b).

¹ Standing declarations are included in an addendum, which is cited as ADD-___.

NRDC also has standing to challenge EPA's denial. Protecting public health from toxic pesticides is germane to NRDC's mission, ADD-08 (Trujillo Decl. ¶¶ 5–6), and neither the asserted claims nor the relief requested in this matter requires the participation of individual NRDC members. See Friends of the Earth, Inc. v. Laidlaw Env't Servs., Inc., 528 U.S. 167, 181 (2000). NRDC members would have standing to sue in their own right: EPA's refusal to cancel TCVP pet collars' registrations injures NRDC members whose young children risk being exposed to the dangerous pesticide. ADD-10–12 (Pontoriero Decl. ¶¶ 1–9); ADD-13–16 (Kruze Decl. ¶¶ 1–11); see NRDC v. EPA (Nanosilver I), 735 F.3d 873, 878–79 (9th Cir. 2013). NRDC members who work with other people's pets also cannot avoid exposure to TCVP. ADD-17–21 (Owens Decl. ¶¶ 1–20); see NRDC v. FDA, 710 F.3d 71, 81–85 (2d Cir. 2013). Ten percent of households with dogs and cats use TCVP products, 2-ER-242, and TCVP collars represent roughly half of all pet collar sales in the United States, see 1-ER-030. Given TCVP's prevalence and the acknowledged health risks that these products pose, NRDC members face at least a "credible threat of harm" from TCVP exposure. Nat'l Family Farm Coal. v. EPA (Enlist Duo), 966 F.3d 893, 909 (9th Cir. 2020) (quoting Cent. Delta Water Agency v. United States, 306 F.3d 938, 950 (9th Cir. 2002)).

A favorable decision from this Court would redress these injuries. Requiring EPA to correct the significant errors in its risk assessment "may influence the agency's ultimate decision." Enlist Duo, 966 F.3d at 910 (quoting Salmon Spawning & Recovery All. v. Gutierrez, 545 F.3d 1220, 1226–27 (9th Cir. 2008) (emphasis in original)). In

fact, if EPA fixed the miscalculations described below, the agency would find ongoing risks of concern to children. *See* ADD-29–31 (Rotkin-Ellman Decl. ¶¶ 23–26). Thus, under EPA's own risk assessment framework, the dangers posed by TCVP collars warrant cancellation of their registrations.

ISSUES PRESENTED

- 1. Did EPA err in determining that TCVP pet collars do not pose an unreasonable risk to children when it miscalculated the ratio of liquid TCVP to dust TCVP in collars?
- 2. Did EPA err in determining that TCVP pet collars do not pose an unreasonable risk to children when it assumed, without substantial evidence, that all pet owners will trim off 20% of their pets' collars?

STATUTES AND REGULATIONS

Pertinent statutory provisions are set forth in an addendum to this brief.

STATUTORY FRAMEWORK

The Federal Insecticide, Fungicide, and Rodenticide Act tasks EPA with regulating the distribution, sale, and use of pesticides. 7 U.S.C. § 136a(a). "Before any pesticide can be sold or used in the United States, EPA must register the pesticide—that is, provide a license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used within the United States." *Enlist Duo*, 966 F.3d at 912. "EPA may not register a pesticide unless the pesticide will perform its intended function without causing 'any unreasonable adverse effects on

the environment." Nw. Coal. for Alternatives to Pesticides v. EPA, 544 F.3d 1043, 1045 (9th Cir. 2008) (quoting 7 U.S.C. § 136a(c)(5)(C)). The Act defines "unreasonable adverse effects on the environment" as "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).

"Any interested person may petition the EPA to cancel a registered pesticide." *In re NRDC*, 956 F.3d at 1136. If EPA concludes that a registered pesticide "generally causes unreasonable adverse effects on the environment," it may initiate proceedings to cancel the registration. 7 U.S.C. § 136d(b).

STATEMENT OF THE CASE

Exposure to TCVP harms children's developing brains

TCVP belongs to a dangerous class of pesticides called organophosphates, 1-ER-055, which are chemically similar to nerve warfare agents, like sarin gas, developed during World War II, see NRDC v. EPA (Dichlorvos), 658 F.3d 200, 205 (2d Cir. 2011); ADD-23 (Rotkin-Ellman Decl. ¶ 4). Organophosphates are highly toxic to the nervous systems of both pests (e.g., fleas and ticks) and humans. People exposed to organophosphates can experience nausea, dizziness, confusion, convulsions, involuntary urination and defecation, and, at high enough doses, respiratory paralysis and death. 2-ER-207, 239.

Organophosphates present a particularly severe threat to children because kids' nervous systems, and especially their developing brains, are more vulnerable to

disruption and their bodies are less capable of metabolizing harmful chemicals. ADD-24 (Rotkin-Ellman Decl. ¶ 7). Drawing on a host of studies, EPA has found that organophosphate exposure is linked to a range of adverse neurodevelopmental outcomes in children, including impaired and delayed mental development, attention disorders, and lowered IQ scores. 2-ER-124–27; *cf. In re Pesticide Action Network N. Am.*, 798 F.3d 809, 814 (9th Cir. 2015) (discussing EPA findings regarding "dangers to human health posed" by another organophosphate pesticide, chlorpyrifos).

EPA nonetheless has allowed TCVP to be used in the home—in the form of household pet products, like flea and tick collars for dogs and cats—where children are exposed to it when they pet or play with treated pets. *See* 1-ER-020–22.² Once a TCVP pet collar is secured around the neck of a dog or cat, the pesticide diffuses from the plastic collar onto the animal's fur. 2-ER-137–38. Children who touch treated pets get TCVP on their hands. *See* 1-ER-068. Then, when they put their hands in their mouths—as toddlers are wont to do—they ingest the pesticide. *Id.* Research suggests that toddlers engage in such mouthing activities an average of roughly twenty times each hour. 2-ER-210; *see also* 2-ER-147.

² These TCVP products are among the last remaining uses of organophosphates inside the home, and the only one to which a toddler would have regular exposure. The other remaining in-home use is for unoccupied areas, like garages and attics. ADD-26 (Rotkin-Ellman Decl. ¶ 13).

NRDC petitions EPA to cancel the registrations of TCVP pet products

When EPA last approved the registrations of TCVP pet products in 2006, it acknowledged that children are exposed to the pesticide by interacting with treated pets. *See* 2-ER-263. EPA, however, failed to conduct *any* analysis of the risks to children from TCVP pet collars. 2-ER-209. It still somehow concluded that TCVP was safe for use on pets. 2-ER-265.

A peer-reviewed study documented risks where EPA had refused to look. Published in 2008, the study found TCVP on the clothing of children living with dogs wearing TCVP collars and also detected a TCVP metabolite (or breakdown product) in the kids' urine. 2-ER-236–37. It further showed that petting a dog wearing a TCVP collar transfers significant amounts of the pesticide onto a person's hands. *Id.* The study warned that there are potentially "millions of children who could be in direct contact" with TCVP via their pets. 2-ER-232.

Based on this and other studies, NRDC petitioned EPA in 2009 to cancel the registrations of TCVP pet products. NRDC's petition pointed out flaws in EPA's previous risk assessment and explained why the scientific literature demonstrated that TCVP pet collars exposed children to unsafe levels of the pesticide. 2-ER-209–12. Meanwhile, other flea and tick control products are effective and available at a comparable cost, but without TCVP's severe risks to children. *See* 1-ER-029–33; 2-ER-227–28; ADD-20–21 (Owens Decl. ¶¶ 17–18); ADD-26–27 (Rotkin-Ellman Decl.

¶ 14). NRDC's petition therefore argued that the unreasonable risks posed by TCVP pet collars merited cancellation of their registrations. See 7 U.S.C. §§ 136d(b), 136(bb).

EPA denies NRDC's petition, but does not defend its flawed decision

NRDC waited five years without a response from EPA. In 2014, NRDC sought a writ of mandamus to compel an answer. Am. Pet. for Writ of Mandamus, *In re NRDC*, No. 14-1017 (D.C. Cir. Apr. 8, 2014), ECF No. 1487402. Only then did EPA deny the cancellation petition. 2-ER-178.

As in its 2006 risk assessment, EPA's 2014 denial of NRDC's petition underestimated the risks to children from TCVP pet collars. Among other flaws, EPA's 2014 risk assessment mistakenly assumed that the TCVP in pet collars is released entirely as a liquid, even though product labels approved by EPA state that the collars release TCVP as a dust. *See* 2-ER-137, 171; 7 U.S.C. § 136a(c)(5)(B). The liquid-dust distinction matters to EPA because the agency assumes that liquid pesticides cling to pets' fur more stubbornly than dust pesticides and thus are less readily transferred from treated animals onto people.³ ADD-29 (Rotkin-Ellman Decl. ¶ 21). In short, EPA believes that TCVP in dust form poses greater health risks than TCVP in liquid form. *See* Decl. of Mary Elissa Reaves ¶ 20, *In re NRDC*, 956 F.3d 1134 (9th Cir. 2020) (No. 19-71324), ECF No. 13-2 [hereinafter Reaves Decl.].

³ EPA's risks assessments carry out this assumption through "transfer coefficients" that quantify the portion of pesticide transferred each hour from a pet wearing a collar to a hand touching the animal. EPA uses a much larger transfer coefficient for dust TCVP (38,000 cm²/hr) than for liquid TCVP (1400 cm²/hr). 1-ER-077.

Consequently, under EPA's methodology, its incorrect assumption that the TCVP in pet collars was released entirely as a liquid significantly understated the risks from those products.

NRDC filed a petition for review in this Court challenging EPA's 2014 refusal to cancel TCVP's registrations for use on household pets. *See In re NRDC*, 956 F.3d at 1137 (discussing prior petition for review). EPA did not defend its decision. Instead, it sought a voluntary remand to reassess TCVP's risks. *Id.* NRDC asked the Court to impose a deadline for EPA to act on remand. *Id.* Opposing that request, EPA informed the Court that it would respond to NRDC's petition within 90 days of finalizing a revised risk assessment. *Id.* The Court remanded the matter to EPA without a deadline. *Id.*

EPA finds that TCVP pet collars endanger children, but then fails to act

In 2016, EPA issued a final revised risk assessment for TCVP that, after correcting several errors from the earlier assessment, found risks of concern to children's health from all TCVP collars. *See* 2-ER-145.

In the revised risk assessment, EPA acknowledged that the TCVP released from pet collars is not entirely liquid. 2-ER-137–39. Instead, the agency found that both liquid TCVP and dust TCVP could be on the fur of a dog or cat wearing a TCVP collar. *Id.* EPA did not know the precise proportion of liquid to dust TCVP released by the collars, because the product manufacturer Hartz had not provided such information. *See* 2-ER-139. So, instead, the agency evaluated collars' risks

assuming three different liquid-dust ratios: 99%-1%, 50%-50%, 1%-99% liquid-dust. *Id.* The risk posed by these formulations increased with the proportion of dust, but EPA found risks of concern to children's neurodevelopment "regardless of the ratio of liquid/dust assumed"—i.e., even when dust comprised only 1% of the collar's TCVP. 2-ER-145; *In re NRDC*, 956 F.3d at 1137, 1140.

EPA declared in the final risk assessment that "there is a need to protect children from exposures that may cause [adverse neurodevelopmental] effects," 2-ER-127, and separately stated that "more stringent regulatory restrictions are necessary to protect public health" from TCVP pet collars, 2-ER-153; *see also* Press Release, EPA Finalizes Human Health Risk Assessment for Pesticide Used on Pets (Jan. 4, 2017), https://www.epa.gov/pesticides/epa-finalizes-human-health-risk-assessment-pesticide-used-pets (announcing that the TCVP risk assessment "identified potential risks to people, including children," that "exceed the Agency's level of concern").

EPA had previously told this Court that it would issue a revised response to NRDC's cancellation petition within 90 days of completing its 2016 risk assessment. *In re NRDC*, 956 F.3d at 1137. But, following a change of administration, EPA did nothing. More than two years after EPA had finalized its risk assessment finding risks of concern from all TCVP collars, and over a decade since NRDC first petitioned the agency to cancel those collars' registrations, NRDC was forced again to seek a writ of mandamus. *Id.* at 1138.

Defending its decade-long delay to this Court, EPA claimed—in an unexplained departure from its prior findings and assurances—that it was "unable to fully respond to NRDC's administrative petition" given "the remaining uncertainty around the physical form of TCVP present in the pet collars (i.e., whether the TVCP in pet collars behaves as a liquid or a solid)." EPA Opp'n to Pet. for Writ of Mandamus at 19–20, *In re NRDC*, 956 F.3d 1134 (9th Cir. 2020) (No. 19-71324), ECF No. 13-1. As noted above, *supra* 10–11, EPA had already found risks of concerns regardless of the liquid-dust ratio in the collars. Nevertheless, the agency insisted that it now needed an additional "torsion study" from Hartz to pin down the precise ratio. Reaves Decl., *supra*, ¶ 23. A torsion study consists of twisting a pet collar and measuring the amount of TCVP dust forced out of the collar. *Id.* According to EPA, this study would provide "the remaining information necessary to its decision" on NRDC's petition. EPA Opp'n to Pet. for Writ of Mandamus, *supra*, at 2. EPA had apparently asked Hartz to conduct this study in 2017, but Hartz declined. *In re NRDC*, 956 F.3d at 1138. Five days after NRDC filed its second mandamus suit in 2019, however, EPA finally ordered Hartz to conduct the torsion study. *Id.*

This Court rejected EPA's excuses for its inaction and issued a writ of mandamus. The Court held that "EPA's years-long delay on this critical matter of public health has been nothing short of egregious" and that EPA has "endanger[ed] the wellbeing of millions of children and ignor[ed] its 'core mission' of 'protecting

human health and the environment." *In re NRDC*, 956 F.3d at 1142–43. The Court ordered EPA to respond to NRDC's petition within 90 days. *Id.* at 1143.

EPA denies NRDC's petition, again

Ninety days after this Court's mandamus ruling, EPA again denied NRDC's cancellation petition. 1-ER-036–40. EPA based this denial on a new, July 2020 revised risk assessment, which made a few changes to the 2016 assessment and found that Hartz could mitigate any remaining risks of concern for TCVP pet collars. As discussed below, these findings in the new 2020 risk assessment are in error.

Like in prior analyses, EPA's 2020 risk assessment determined whether TCVP pet collars present risks of concern by calculating a Margin of Exposure (MOE) for each registered product, and then comparing that to a designated Level of Concern (a threshold for unacceptable risk). See 1-ER-016–17, 056–57. An MOE is equal to the dose of a toxic substance found to cause harm (known as the "point of departure") divided by the dose of the substance that EPA estimates a person will be exposed to: MOE = point of departure / estimated dose. See 2-ER-135, 149; Nanosilver I, 735 F.3d at 881–82 (explaining how EPA calculates an "actual MOE"). An MOE of one indicates that the estimated dose is equal to the point of departure. An MOE of 100, by contrast, indicates that the estimated dose is 100 times lower than the point of departure. Thus, counterintuitively, a higher MOE signals lower risk. Nanosilver I, 735 F.3d at 882.

After calculating an MOE for each registered TCVP collar, EPA then compared those figures to the agency's Level of Concern, which marks its threshold for unacceptable risk. *See* 1-ER-056–57. If EPA could be sure that harm would occur only when a person's dose equals or exceeds the point of departure, EPA would set the Level of Concern at an MOE of one. However, EPA's knowledge about how pesticides like TCVP affect the human body, and the bodies of children in particular, is far from complete. For instance, TCVP's point of departure (2.8 milligrams TCVP per kilogram of body weight per day) is derived from a study on rats. 1-ER-014; 2-ER-130. Using TCVP's effects on rats to predict its effects on children introduces uncertainty into the risk assessment.

To account for such uncertainty, EPA sets its Level of Concern at an MOE greater than one. "This approach is similar to an engineer who estimates that a bridge must hold X weight, and then designs the bridge in a way that she believes will hold 3X weight, to create a margin of safety based on prior engineering practice." *Dichlorvos*, 658 F.3d at 208. For oral exposure to TCVP, EPA's Level of Concern is 1000, meaning it finds risks of concern at MOEs of 1000 or less.⁴ 1-ER-016–17. In other words, to fall outside the risk threshold, toddlers' estimated oral dose of TCVP

⁴ This Level of Concern is derived by applying a 10X uncertainty factor for interspecies variation (the uncertainty created by extrapolating from animal studies to effects on humans), a 10X uncertainty factor for intraspecies variations (accounting for differences among humans), and a 10X uncertainty factor for children's safety (accounting for the special susceptibility of children to pesticides). 1-ER-016–17.

must be less than 0.0028 milligrams per kilogram of body weight per day, or at least 1000 times smaller than the point of departure of 2.8 milligrams per kilogram per day.

EPA's 2020 risk assessment found that all seven of Hartz's TCVP pet collars present risks of concern (MOEs less than 1000) when used on small cats and dogs. 1-ER-026–27, 038, 041–42.⁵ One collar also posed such risks when used on medium-sized dogs, and another when used on a cat of any size. 1-ER-027.

In response, Hartz asked EPA to cancel the registration of one pet collar. 1-ER-038; *see also* 85 Fed. Reg. 86,557 (Dec. 30, 2020) (granting Hartz's requested voluntary cancellation). For the other six collars, Hartz and EPA negotiated mitigation measures aimed at lowering the collars' risks. These measures include reducing the amount of TCVP in the collars, as well as new label restrictions prohibiting some collars' use on small cats. 1-ER-039–42, 101. EPA calculated the products' post-mitigation MOEs, found that they all exceeded 1000, and concluded that the reformulated and relabeled collars would not present risks of concern. 1-ER-100–03; *see also* 1-ER-028, 039–42. In other words, EPA found that Hartz would address its collars' unacceptably high risks through either voluntary cancellation or mitigation,

⁵ Under EPA's risk assessment framework, applying the same amount of pesticide to a smaller pet results in a higher concentration of pesticide on the pet's fur and thus greater exposure for a person touching the animal. *See* 2-ER-196–201. Consequently, EPA separately evaluated risks from TCVP collars for small, medium, and large cats and dogs. 1-ER-017–18, 027.

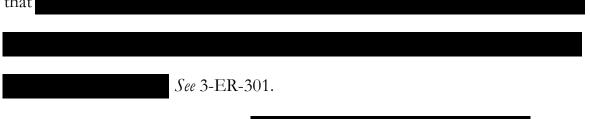
and thus denied NRDC's petition to cancel TCVP pet collars' registrations. 1-ER-038-40.6

EPA's denial exhibits serious flaws, again

EPA, however, did not use

EPA's denial—and the changes it made between the 2016 and 2020 risk assessments—relies heavily on two new studies conducted by Hartz, neither of which was peer reviewed or subject to public comment. EPA botched its use of both studies in the 2020 risk assessment, leading to fundamental errors that undermine the agency's basis for denying NRDC's petition.

The first of the new studies is the torsion study, which EPA compelled Hartz to perform so the agency could determine the relative proportions of liquid and dust TCVP released by Hartz's pet collars. *Supra* 12. In the study, which measured the amount of TCVP dust extruded from a twisted collar, *see* 2-ER-106, Hartz reported that



. Instead,

EPA took the raw data from the torsion study, see 2-ER-109-10, and set out to

⁶ EPA also found that TCVP dust and powder products present risks of concern (MOEs < 1000). 1-ER-037. Hartz has sought and received voluntary cancellation of these products. *Id.*; 85 Fed. Reg. at 86,557. EPA determined that TCVP spray products do not present risks of concern. 1-ER-036–037. This petition for review challenges only EPA's refusal to cancel the registrations for TCVP pet collars.

recalculate the liquid-dust ratio, concluding that the actual ratio was 0.38% dust to 99.62% liquid. 1-ER-018, 065. In revising Hartz's calculation, however, EPA wrongly compared the weight of TCVP dust not just to the weight of TCVP in the collar, as it said it intended to do, but rather to the weight of the entire collar. In fact, the portion of the collar that is not dust is comprised not just of liquid TCVP, but also the plastic that forms the collar's body and various inert ingredients, which are not relevant to the ratio that EPA set out to calculate. See 2-ER-107, 138; see also 1-ER-093 (describing it as a "TCVP-impregnated collar"). Had EPA plugged the correct ratio—the one—into its own formulas, EPA would have found risks of concern from pet collars even after accounting for the mitigation measures negotiated with Hartz. ADD-29–31 (Rotkin-Ellman Decl. ¶¶ 25–26).

EPA also drew on another unpublished Hartz study to revise its prior risk assessment and reject NRDC's petition. The labels for Hartz's TCVP collars instruct pet owners to fit the collar around their pet's neck and then trim off the excess, leaving two to three inches for further adjustment. 1-ER-020, 102. In the 2016 risk assessment, EPA found that it lacked sufficient evidence to determine how much collar, if any, pet owners actually remove. *See* 2-ER-168; 1-ER-068. Consequently, pursuant to its scientific protocol, EPA assessed the risks to children when cats and dogs wear the full TCVP collar. *See* 2-ER-168; 1-ER-068.

In 2020, Hartz submitted a study regarding the efficacy of pet collars containing . 3-ER-

fit medium-sized dogs (all weighing between 11 and 22 kg, or 24 to 48 pounds) with

. 3-ER-273-75, 278-81; 1-ER-021, 068.

then trimmed the collars, removing at least 20% of each collar. 1-ER-021, 068; 3-ER-283, 291-93. Based on this study—which did not include any large dogs, cats,

—EPA scrapped its previous finding that it lacked sufficient evidence to estimate collar removal. Instead, the agency now assumed that all pet owners using any TCVP pet collar would remove at least 20% of the collar, thereby discarding a significant portion of the pesticide active ingredient to which children might otherwise be exposed. 1-ER-021; see also 1-ER-102.

NRDC promptly filed this lawsuit, challenging the denial of its petition to cancel the registrations of TCVP pet collars.

SUMMARY OF ARGUMENT

EPA's denial of NRDC's petition to cancel TCVP pet collars lacks substantial evidence for two reasons, either of which is grounds for vacatur.

First, EPA miscalculated the ratio of liquid TCVP to dust TCVP, a key component of its risk evaluation. The agency significantly underestimated the proportion of TCVP that is released as a dust, which in turn led it to significantly underestimate children's exposure to the pesticide. Had EPA used the correct liquid-dust ratio, it would have found risks of concern to children warranting cancellation of

TCVP pet collars' registrations. By relying on "arbitrary and highly inaccurate calculations," *Trustees of Cal. State Univ. v. Riley*, 74 F.3d 960, 967 (9th Cir. 1996), EPA has "offered an explanation" for its rejection of NRDC's petition "that runs counter to the evidence before the agency," *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Second, EPA underestimated TCVP collars' risks to children by assuming, without evidence (and contrary to the agency's own risk assessment protocol), that every time pet owners fit a collar to their dog or cat, they will trim the collar by at least 20%. EPA's 2016 risk assessment properly concluded that the agency lacked sufficient data to make such an assumption. Its 2020 petition denial reversed course, relying on an inapposite manufacturer study in which fit pet collars on medium-sized dogs. But that study did not even use It offers no insight into how much collar actual pet owners will remove from their pets, including from large dogs, which Hartz omitted from its study. In fact, it will be physically impossible for at least some owners of large dogs to remove 20% of their pet's collar. EPA's petition denial rests on "unsubstantiated assumptions" and thus lacks substantial evidence. NRDC v. EPA (Nanosilver II), 857 F.3d 1030, 1038 (9th Cir. 2017).

The Court should vacate EPA's denial of NRDC's petition and direct EPA to revise its response within 30 days.

STANDARD OF REVIEW

This Court reviews EPA's order for "substantial evidence," 7 U.S.C. § 136n(b), which means "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Nanosilver I*, 735 F.3d at 877 (quoting *Vasquez v. Astrue*, 572 F.3d 586, 591 (9th Cir. 2009)). Substantial evidence review, though "relatively deferential," must still be "searching and careful, subjecting the agency's decision to close judicial scrutiny." *Containerfreight Corp. v. United States*, 752 F.2d 419, 422 (9th Cir. 1985) (internal quotation marks and citation omitted). The agency cannot satisfy its burden through "unsubstantiated assumptions." *Nanosilver II*, 857 F.3d at 1038.

The substantial evidence standard is more stringent than arbitrary and capricious review. *Union Oil Co. of Cal. v. Fed. Power Comm'n*, 542 F.2d 1036, 1041 (9th Cir. 1976); *see Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 533 (9th Cir. 2015) (Smith, N.R., J., concurring) (explaining that if "EPA's pesticide registration [decision] is arbitrary and capricious," the agency "cannot show it was supported by substantial evidence"). Accordingly, EPA's denial of NRDC's petition lacks substantial evidence if EPA failed to "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (quotation marks omitted).

ARGUMENT

I. EPA miscalculated an essential component of its risk evaluation, underestimating TCVP pet collars' risks to children

EPA believes that dust TCVP presents greater risks of exposure than liquid TCVP. *See supra* 9. It therefore insisted to this Court that the ratio of dust TCVP to liquid TCVP released by pet collars is a "necessary" element of its risk assessment. *See* EPA Opp'n to Pet. for Writ of Mandamus, *supra*, at 2, 11–12; Reaves Decl., *supra*, ¶ 23. Rather than determining *that* ratio, however, as EPA set out to do, 1-ER-065, the agency instead calculated the ratio of the collar's dust to *the rest of the entire collar*—its plastic body, inert ingredients, and liquid TCVP. The agency's "arbitrary and highly inaccurate calculations" skewed the outcome of its risk assessment, *Trustees*, 74 F.3d at 967, causing EPA to substantially underestimate TCVP pet collars' threat to children's health. Therefore, EPA's risk assessment fails on its own terms. The Court can "judge the validity" of EPA's petition denial simply "by examining whether [EPA] in fact calculated that which it sought to calculate." *Ala. Power Co. v. FCC*, 773 F.2d 362, 367 (D.C. Cir. 1985). EPA plainly did not.

EPA claimed that it needed the torsion study from Hartz "to address the uncertainty surrounding the ratio of liquid/dust in the TCVP pet collars." 1-ER-065; see also In re NRDC, 956 F.3d at 1137–38; EPA Opp'n to Pet. for Writ of Mandamus, supra, at 2, 19–20; Reaves Decl., supra, ¶¶ 22–23. The torsion study submitted by Hartz showed that the liquid-dust ratio of TCVP is

305–06. But without any explanation, EPA set out to calculate its own.

EPA began this misadventure by noting, correctly, that the torsion study showed that 0.38% of the collar's weight is released as a dust. 2-ER-107. EPA then jumped to the illogical conclusion that only 0.38% of the TCVP in the collar is released as a dust. 1-ER-018, 065. But EPA failed to account for the fact that liquid and dust TCVP together make up only a small portion of the collar's overall weight—less than 15%. 2-ER-106. The majority of the collar's weight comes from plastic and inactive ingredients. *Id.*; 2-ER-138. The specific calculations are set out below, but EPA's error is clear as a matter of logic and basic math: If dust makes up 0.38% of the collar's total weight (plastic and all), and only a portion of the collar is made up of TCVP, then dust must make up more than 0.38% of the weight of TCVP in the collar. Put another way, in purporting to calculate the percentage of TCVP in collars that is released as dust, EPA used the wrong denominator.

EPA's error is akin to concluding that, because 10% of the *pets* in a town are Golden Retrievers, 10% of the *dogs* in the town are Golden Retrievers. But dogs are only a subset of the pet population. (Cats and goldfish also inhabit our hypothetical town.) Thus, if Golden Retrievers make up 10% of the overall pet population, they must make up more than 10% of the dog population. So too here, EPA has artificially lowered the percentage of dust TCVP by calculating it with respect to the overall weight of the collar, rather than just the portion of the collar comprised of TCVP.

Similar to its error in the 2014 risk assessment where EPA wrongly assumed that the TCVP released by pet collars is entirely liquid, *supra* 9, EPA has—under its own methodology—once again underestimated collars' risks by overstating the proportion of the active ingredient in liquid form.

Next, EPA should have divided the weight of extruded TCVP dust by the weight of TCVP in the collar to learn the proportion of TCVP's weight that was released as dust, rather than liquid. Because TCVP makes up 14.33% of the collar's weight, 2-ER-107, the TCVP in the collar weighs 5101.48 mg (0.1433 x 35,600 mg). Dividing the weight of the TCVP dust (129.94 mg) by the weight of TCVP in the

⁷ For ease of reference, all weights are given in milligrams (mg). 1 gram = 1000 mg.

collar (5101.48 mg) reveals that 2.55% of the TCVP in the collar is released as a dust. The remaining 97.45% of TCVP is assumed to be released as a liquid. The ratio EPA claimed to be looking for is therefore 97.45% liquid to 2.55% dust. As noted above,

. 3-ER-301, 305–06.

EPA's 2020 risk assessment, however, never factored in the weight of the TCVP in the collar.⁸ Instead, EPA divided the weight of dust it had wrongly calculated to be extruded from the collar (133.9 mg) by the total weight of the collar (35,600 mg) to conclude that dust makes up 0.38% of the *collar's total* weight. 2-ER-107, 109. This "irrelevant percentage" is not the figure that EPA set out to calculate. *Ala. Power*, 773 F.2d at 368. Nevertheless, EPA claimed it had found the percentage of TCVP in pet collars released as dust and declared that the remaining 99.62% was liquid. 1-ER-069 (stating that EPA "assumed a liquid/dust ratio of 99.62/0.38"); 1-ER-065 (same). EPA then fed this faulty ratio into the rest of its risk equations. 1-ER-

⁸ EPA, notably, did account for the fact that TCVP makes up less than 15% of a collar's weight when making other calculations in the risk assessment, such as when it relied on a Hartz study that measured the proportion of TCVP in a collar that transferred from a dog to a gloved hand petting the animal. *See* 1-ER-024 ("Percent transferable residues of TCVP were calculated by taking the ratio of the residues of TCVP observed on the glove to the total amount of TCVP in the collar at application (calculated as the percent TCVP * initial weight of collar)."); *see also* 1-ER-070, 093–94. It is not clear why EPA failed to make this same simple adjustment of multiplying the percent TCVP by the initial weight of the collar when calculating the liquid-dust ratio. *See Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1141 (9th Cir. 2015) (An agency's "internally inconsistent analysis is arbitrary and capricious.").

022. EPA's calculation errors in determining the proportion of TCVP that is dust are illustrated in the following table:

Summary of EPA's Calculation Errors

EPA's calculation	What EPA should have done
7.5 mg (average amount of dust lost from torsion of test strip) x 17.8 (scaling factor)	7.3 mg (average amount of TCVP dust lost from torsion of test strip) x 17.8 (scaling factor)
= 133.9 mg ((incorrect) estimate of dust that would be lost from full collar)	= 129.94 mg (estimate of TCVP dust that would be lost from full collar)
Weight of full collar	35,600 mg (collar's weight) x .1433 (fraction of the collar's weight that is TCVP)
= 35,600 mg	= 5101.48 mg (weight of TCVP in collar)
133.9 mg (extruded dust) 35,600 mg (collar's weight)	129.94 mg (extruded TCVP dust) 5101.48 mg (weight of TCVP in collar)
= 0.38%	=2.55%

In short, "[t]he fraction used by [EPA] . . . bears no rational relationship to the determination it purport[ed] to make." *Ala. Power*, 773 F.2d at 370. EPA's "somewhat casual calculations exhibit at several points the sort of 'clear errors of judgment,' and absence of 'rational connections between the facts found and the choices made,' that render an order arbitrary and capricious." *Id.* at 372 (alterations and citations omitted); *see also Trustees*, 74 F.3d at 966–67 (agency acted arbitrarily by using an inaccurate and self-serving method to calculate the interest owed to it); *Clean Wis. v. EPA*, 964 F.3d 1145, 1169 (D.C. Cir. 2020) (EPA's "central reliance" on an "apparently mistaken"

interpretation of data is arbitrary and capricious); Native Vill. of Chickaloon v. Nat'l Marine Fisheries Serv., 947 F. Supp. 2d 1031, 1056 (D. Alaska 2013) (agency's "calculations are clearly erroneous," and thus arbitrary and capricious, where they "fail[] to adequately calculate that which the agency was actually trying to calculate").

EPA's "substantial mathematical errors" are not harmless. Hermes Consol., LLC v. EPA, 787 F.3d 568, 579 (D.C. Cir. 2015). They "significantly alter important figures in EPA's independent analysis" such that the Court "cannot conclude with sufficient certainty that the agency would have made the same decision absent its errors." Id. EPA previously told this Court that the liquid-dust ratio was the critical missing piece of information it needed to answer NRDC's petition. EPA Opp'n to Pet. for Writ of Mandamus, supra, at 2, 19–20; Reaves Decl., supra, ¶ 23. EPA insisted that dust TCVP presents greater risks than liquid TCVP, Reaves Decl., supra, ¶ 20, yet EPA's miscalculation led it to underestimate the proportion of dust TCVP by a factor of more than six.9

This error cascaded throughout EPA's risk assessment. The wrong liquid-dust ratio yielded the wrong amount of TCVP on children's hands, which yielded the wrong amount of TCVP in children's bodies, which yielded the wrong MOEs and, ultimately, the wrong conclusion about the risk to children from TCVP collars. ADD-29–31 (Rotkin-Ellman Decl. ¶¶ 22–26). EPA's prior risk assessment found risks of

 $^{^{9} 2.55\% / 0.38\% = 6.71.}$

concern when the TCVP released by collars is only 1% dust. 2-ER-145. Now, the data before the agency show that the TCVP released by these collars is 2.55% dust. Had EPA used the correct liquid-dust ratio of 97.45% to 2.55%, rather than 99.62% to 0.38%, it would have found risks of concern for all pet collars even after mitigation measures. ADD-29–31 (Rotkin-Ellman Decl. ¶¶ 25–26); *cf. Nanosilver I*, 735 F.3d at 881–84 (holding that EPA's determination that a pesticide did not pose risks of concern lacked substantial evidence because EPA's own calculations indicated that the pesticide did pose a risk of concern).

EPA's miscalculation of the ratio at the core of its risk assessment means that the agency has failed to articulate a "rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (citation omitted). EPA's refusal to cancel the registrations of TCVP pet collars therefore lacks substantial evidence.

II. EPA lacks substantial evidence for its assumption that all pet owners will trim TCVP collars by 20%

Reversing its position from a previous risk assessment, EPA now assumes that all pet owners will trim their TCVP collars by 20%, thereby reducing children's exposure to the pesticide. 1-ER-021. Not only does EPA lack "good reasons" for its about-face, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (internal quotation marks omitted), its assumption also "runs counter to the evidence before the agency," *State Farm*, 463 U.S. at 43, and thus is not supported by substantial evidence.

TCVP pet collar labels instruct owners to fit the collar around their dog's or cat's neck and then cut off the excess, leaving two to three inches for future adjustment. 1-ER-020, 102. When preparing its 2016 risk assessment, EPA could not find any available data indicating the exact length that is cut off. *See* 2-ER-168; 1-ER-068. Thus, consistent with EPA's risk assessment protocol, it assumed that individuals would be exposed to the full length of the collar. 2-ER-168; 1-ER-068.

In its 2020 decision, however, EPA rejected NRDC's petition based in part on the new assumption that all pet owners will remove 20% of their dog or cat's collar. 1-ER-021. This assumption drops the amount of TCVP to which EPA estimates children will be exposed, *see* 1-ER-102, and so lowers collars' estimated risks. An inapposite study submitted by Hartz serves as EPA's sole justification for abandoning its prior determination that it could not predict the amount of collar removed. EPA found that dogs' collars fitted in that study where shortened by at least 20%. 1-ER-021. This study—which was conducted for an entirely different purpose, tested on only medium-sized dogs, and was never made available for public comment—does not support EPA's assumption.

To start with, EPA failed to acknowledge that its new removal assumption departs from the agency's own risk assessment protocol, which states that "the maximum application rate of the collar as labeled should be assumed for assessment of post-application risk." 2-ER-201. The protocol explains that this no-removal assumption is appropriate "[b]ecause the trimmed length and corresponding active

ingredient loss cannot be determined." *Id.* This seems to reflect EPA's common-sense judgment that it is impossible to predict whether millions of individual pet owners will remove any portion of a pet collar, let alone the precise amount they might cut back. EPA adhered to this protocol in its 2016 risk assessment when it found risks of concern from TCVP collars, 2-ER-168, but abandoned it four years later when denying NRDC's petition. EPA offers no "good reasons" for jettisoning its own protocol. Encino Motorcars, 136 S. Ct. at 2126. In fact, EPA's 2020 decision does not even acknowledge that it is deviating from the agency's protocol. Consequently, EPA's unexplained and "irrational departure" from the "general policy" announced in its protocol "must be overturned." INS v. Yueh-Shaoi Yang, 519 U.S. 26, 32 (1996). An agency that changes course "must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored." *Physicians* for Soc. Responsibility v. Wheeler, 956 F.3d 634, 647 (D.C. Cir. 2020) (quoting Lone Mountain Processing, Inc. v. Sec'y of Labor, 709 F.3d 1161, 1164 (D.C. Cir. 2013)).

Even assuming manufacturer-supplied data could justify departing from the agency's protocol in certain circumstances, Hartz's study here does not—for several reasons. For one thing, the study involved no

the agency does not even acknowledge the critical point that

See 1-ER-021, 068. Nor does the study indicate how the

Compare 1-ER-020,

102 (noting that TCVP collar labels instruct users to leave two to three inches of extra

collar), with 3-ER-283

Consequently, EPA's calculation that had 20—

43% removed, 1-ER-021, provides no insight whatsoever into the proportion likely to

be removed from . This study is completely

irrelevant.

See 3-ER-271

. Why would the length of collar snipped off by shed any light on the amount of collar likely to be removed by a typical person grappling with their squirmy dog or cat on a kitchen floor? Perhaps, rather than cutting off the excess, some pet owners will secure the collar's loose end by tucking it behind the collar's loop, a possibility raised by EPA's Human Studies Review Board. 2-ER-158. EPA has no idea because it has no data about real-world pet owners. EPA could have solicited public comment on the question and its reliance on the Hartz study, but it did not.

In addition, Hartz's study did not observe

EPA's 2020 decision also fails to acknowledge that Hartz's study omits several relevant categories of pets. It therefore cannot justify EPA's blanket assumption that all pet owners will trim off 20% of TCVP collars. For example, the Hartz study included no small or large dogs. EPA assesses the risks from pet collars separately for

animals of different sizes. 1-ER-017–18, 027; *supra* 15 n.5. EPA defines small dogs as weighing up to 20 pounds, medium dogs as weighing between 21 and 50 pounds, and large dogs as weighing over 51 pounds. 1-ER-018. But the dogs in Hartz's study all weighed between 11 and 22 kilograms, 1-ER-021, or between 24 and 48 pounds, and the study included only

3-ER-275, 295–96.

Nevertheless, EPA incorporated the 20% collar removal assumption into its assessment of the risk from TCVP collars used on *all* dogs, including small and large ones. 1-ER-101–02 (Registration Nos. 2596-50, -62, -84, -139). The agency gave no explanation for doing so.¹⁰

The absence of large dogs from Hartz's study should have piqued EPA's curiosity. Large dogs are likely to have larger necks than the medium dogs in Hartz's study, resulting in less collar being removed. As it turns out, evidence *directly contradicting the 20% removal assumption* was right in front of the agency. Hartz's own website advertises at least one of its TCVP collars as fitting dogs with "necks that measure up to 26 [inches]." Hartz, Hartz® UltraGuard Flea & Tick Collar for Large Dogs, https://www.hartz.com/product/hartz-ultraguard-flea-and-tick-collar-for-large-dogs/ (last visited Feb. 9, 2021). The maximum length of that collar is reported

O The Hartz study als

¹⁰ The Hartz study also included no cats or cat collars. *See* 1-ER-021. Yet, EPA applied the 20% removal assumption to pet collars registered for use on cats. 1-ER-102 (Registration Nos. 2596-49, -83, and -139). Again, it offered no explanation.

¹¹ NRDC respectfully requests that the Court take judicial notice of the fact that Hartz's website advertises this product as fitting dogs with necks up to 26 inches. This

as 27 inches. 1-ER-102–03. The owner of a dog with a 26-inch neck could remove at the very most 1 inch of this collar, or about 4%. And if that owner tried to follow the instruction to leave at least 2 to 3 inches for future adjustment, 1-ER-102, they physically could not remove any portion of the collar at all. See also ADD-32 (Rotkin-Ellman Decl. ¶¶ 27–32) (describing labeling and length of Hartz's UltraGuard Flea & Tick Collar for Large Dogs). Whether EPA was aware of these facts and ignored them, or it simply never bothered to look, its 20% removal assumption is clearly erroneous and arbitrary and capricious. Nat'l Family Farm Coal. v. EPA (Dicamba), 960 F.3d 1120, 1144 (9th Cir. 2020) (EPA's pesticide registrations lacked substantial evidence where EPA ignored evidence of the pesticide's risks and costs); Or. Nat. Desert Ass'n v. Jewell, 840 F.3d 562, 570 (9th Cir. 2016) (agency's conclusion that an endangered species would not be present at a location was arbitrary because it was not "based on accurate information and defensible reasoning").

In short, EPA offers no "good reasons" for jettisoning its previous finding that it lacked sufficient data to estimate a precise collar removal amount. *Encino Motorcars*, 136 S. Ct. at 2126. The agency does not even acknowledge that it is deviating from its risk assessment protocol or that it is extrapolating from a

fact "can be accurately and readily determined from" Hartz's website, and it "cannot reasonably be questioned" that the website accurately communicates Hartz's claims about its own products. Fed. R. Evid. 201(b)(2); see O'Toole v. Northrop Grumman Corp., 499 F.3d 1218, 1224–25 (10th Cir. 2007) (district court erred by refusing to take judicial notice of information on a corporate defendant's website).

dogs and cats of all sizes. EPA has no reliable evidence to support its removal

assumption. EPA's petition denial rests on an "unsubstantiated assumption" and therefore lacks substantial evidence. *Nanosilver II*, 857 F.3d at 1038.

III. EPA's petition denial should be vacated and remanded for a revised response within 30 days

EPA's denial of NRDC's petition to cancel the registrations of TCVP pet collars lacks substantial evidence and should be "set aside." 7 U.S.C. § 136n(b). 12 EPA's errors go to the heart of its risk assessment and caused it to underestimate significantly TCVP pet collars' risks to children. ADD-29–31 (Rotkin-Ellman Decl. ¶¶ 25–26).

Further, given the history of this matter and the ongoing risks to children's health, the Court should order EPA to issue a revised final response to NRDC's petition within 30 days. *See Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 937 (9th Cir. 2008) (discussing courts' "discretionary authority to impose a deadline for [agency] remand proceedings"). When the Court last remanded this matter to EPA without a deadline in 2016, years of delay ensued, requiring NRDC to burden this Court by seeking a writ of mandamus (for the second time). *In re NRDC*,

¹² NRDC seeks vacatur of the portion of EPA's petition denial refusing to cancel the registrations of pet collar products with Registration Nos. 2596-49, -50, -62, -83, -84, and -139. NRDC does not seek vacatur of the portions of EPA's petition denial addressing other TCVP pet products. *Supra* 16 n.6.

956 F.3d at 1137–38. EPA's pattern of "broken promises," casual mistakes, and "egregious" delay makes the need for a deadline on this remand painfully clear. *Id.* at 1142–43. The agency's recent erroneous liquid-dust ratio and collar removal assumption based on a wholly irrelevant study demonstrate that EPA was at best negligent in its revised risk assessment. For a dozen years and counting, EPA has "endanger[ed] the wellbeing of millions of children and ignor[ed] its 'core mission' of 'protecting human health and the environment'" by failing to conduct an evidence-based assessment of TCVP's risks. *Id.* at 1143 (citation omitted). Thankfully, fixing the errors in EPA's most recent risk assessment is a straightforward task that can be accomplished quickly. *See, e.g.*, ADD-29–31 (Rotkin-Ellman Decl. ¶ 25). The Court should order EPA to do so within 30 days.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for review and vacate EPA's denial of NRDC's petition to cancel the registrations of TCVP pet collars. The Court should further order EPA to issue a revised response to NRDC's petition within 30 days, either by granting the petition and initiating cancellation proceedings or by denying the petition. If EPA initiates cancellation proceedings, the Court should order EPA to submit regular status reports describing the progress of those proceedings. *See In re NRDC*, 956 F.3d at 1143.

Dated: February 16, 2021 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of 9th Cir. R. 32-1(a) because it contains 8930 words, excluding the parts of the brief exempted by 9th Cir. R. 32-1(c) and Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using 14-point Garamond font.

Dated: February 16, 2021	/s/ Ian Fein	
	Ian Fein	