FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NORTHWEST COALITION FOR ALTERNATIVES TO PESTICIDES (NCAP), *Petitioner,* v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *Respondent,* CROPLIFE AMERICA, *Intervenor.*	No. 05-75255 EPA No. Clear Air Act
NATURAL RESOURCES DEFENSE COUNCIL, INC., *Petitioner,* v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *Respondent.*	No. 05-76807 EPA No. 70 Fed Reg 46706 OPINION

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

Argued and Submitted
June 6, 2007—Seattle, Washington

Filed September 19, 2008

Before: Harry Pregerson and Sandra S. Ikuta, Circuit Judges, and Barry T. Moskowitz,* District Judge.

Opinion by Judge Pregerson;
Partial Concurrence and Partial Dissent by Judge Ikuta

*The Honorable Barry T. Moskowitz, District Judge for the Southern District of California, sitting by designation.

COUNSEL

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Jonathan J. Fleuchaus, Environmental Protection Agency, Washington, D.C.; Sue Ellen Woodridge, Attorney General, John C. Cruden, Deputy Assistant Attorney General, and Kent E. Hanson, Environment and Natural Resources Division, United States Department of Justice, Washington, D.C., for respondent-appellee Environmental Protection Agency.

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OPINION

PREGERSON, Circuit Judge:

Petitioners are two environmental groups challenging the Environmental Protection Agency's ("EPA") establishment of tolerances for seven pesticides used mostly on fruit and vegetable crops. We grant the petition in part, deny it in part, and remand to the EPA.

BACKGROUND

I.

The EPA regulates pesticides under two statutes: the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136-136y, and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 346a.

Under FIFRA, pesticides sold in the United States must be registered by the EPA. 7 U.S.C. § 136a. The EPA may not register a pesticide unless the pesticide will perform its intended function without causing "any unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C).

The FDCA authorizes the EPA to set "tolerances" for pesticide residues in food. 21 U.S.C. § 346a(b). "A tolerance is the maximum allowable amount of pesticide that may remain in or on a commodity." *Nader v. EPA*, 859 F.2d 747, 748 (9th Cir. 1988). The EPA may "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if [the EPA] determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i). The term "safe" is defined to mean 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." 21 U.S.C.

§ 346a(b)(2)(A)(ii). Any tolerance that is not "safe" must be modified or revoked. 21 U.S.C. § 346a(b)(2)(A)(i).

Tolerances are established by rulemaking. 21 U.S.C. § 346a(d). Pesticide manufacturers initiate the rulemaking process by petitioning the EPA to set a tolerance. 21 U.S.C. § 346a(d)(1). The EPA publishes notices of these petitions in the Federal Register. 21 U.S.C. § 346a(d)(3). After reviewing a petition and any comments received on it, the EPA may issue: (1) a final rule establishing a tolerance, (2) a proposed rule, or (3) an order denying the petition. 21 U.S.C. § 346a(d)(4).

Once the EPA takes final action on a petition, any affected party has sixty days to file objections with the EPA and to seek an evidentiary hearing on those objections. 21 U.S.C. § 346a(g)(2). The EPA's final order in response to those objections is subject to judicial review. 21 U.S.C. § 346a(h)(1).

II.

In 1996, Congress amended the FDCA by enacting the Food Quality Protection Act ("FQPA"), Pub. L. No. 104-170, 110 Stat. 1489. One of the key provisions of the FQPA requires the EPA to give special consideration to risks posed to infants and children when establishing pesticide tolerances. Specifically, the FQPA directs the EPA to use "an additional[1] tenfold margin of safety . . . to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." 21

[1]This margin of safety is "additional" to two safety factors that the EPA has long used to account for other uncertainties: a tenfold factor for inter-species differences (to account for the possibility that people are more susceptible than animals studied in laboratory experiments), and a tenfold safety factor for intra-species differences (to account for the wide range of sensitivities in the human population).

U.S.C. § 346a(b)(2)(C). This tenfold (or "10x") child safety factor is presumptively applied to all tolerances. Thus, in making tolerance decisions, the EPA must assume that the risk to children from the use of a particular pesticide on food is ten times greater than for adults. The EPA may "use a different margin of safety for the pesticide chemical residue *only if, on the basis of reliable data*, such margin will be safe for infants and children." *Id.* (emphasis added).

Unfortunately, the FQPA does not define "reliable data." The dispute before us turns on the definition of this term.

Between December 2001 and April 2002, the EPA published seven regulations establishing tolerances for the pesticides acetamiprid, fenhexamid, halosulfuron-methyl, isoxadifen-ethyl, mepiquat, pymetrozine, and zeta-cypermethrin used on many foods, including fruits, vegetables, nuts, cereal grains, milk, and eggs.[2] Each regulation was promulgated in response to an industry petition to establish tolerances.

The EPA did not apply the presumptive 10x child safety factor to any of these seven pesticides. The EPA reduced the 10x child safety factor to 3x for four of the pesticides (acetamiprid, fenhexamid, isoxadifen-ethyl, and pymetrozine). For the remaining three pesticides (halosulfuron, mepiquat, and zeta-cypermethrin), the EPA did not apply a child safety factor at all.

[2]For the EPA's individual tolerance rulings, see Acetamiprid; Pesticide Tolerance, 67 Fed. Reg. 14,649 (Mar. 27, 2002); Fenhexamid; Pesticide Tolerance, 67 Fed. Reg. 19,114 (Apr. 18, 2002); Halosulfuron-methyl; Pesticide Tolerance, 66 Fed. Reg. 66,333 (Dec. 26, 2001); Isoxadifen-ethyl; Pesticide Tolerance, 67 Fed. Reg. 12,875 (Mar. 20, 2002); Mepiquat; Pesticide Tolerance, 67 Fed. Reg. 3,113 (Jan. 23, 2002); Pymetrozine; Pesticide Tolerance, 66 Fed. Reg. 66,786 (Dec. 27, 2001); Zeta-cypermethrin and its Inactive R-isonomers; Pesticide Tolerance, 67 Fed. Reg. 6,422 (Feb. 15, 2002).

In 2002, Natural Resources Defense Council, Inc. ("NRDC") filed objections to each of the tolerances based on the EPA's decision to reduce or remove the child safety factor.[3] NRDC argued that the EPA did not have "reliable data" allowing it to deviate from the child safety factor.

On August 10, 2005, the EPA issued its final order rejecting NRDC's objections. *See* Order Denying Objections to Issuances of Tolerances, 70 Fed. Reg. 46,706 (Aug. 10, 2005) (hereinafter "Final Order"). The Final Order upheld the 3x child safety factor for acetamiprid, fenhexamid, isoxadifen-ethyl, and pymetrozine, and a 1x child safety factor (i.e., *no* safety factor) for halosulfuron, mepiquat, and zeta-cypermethrin. *Id.* at 46,711-13, 46,736.

NRDC and the Northwest Coalition for Alternatives to Pesticides ("NCAP") each petitioned for review of the Final Order.

JURISDICTION

We have jurisdiction under the FDCA, which provides that "any person who will be adversely affected" by an EPA order denying tolerance objections may file a petition for review in the Court of Appeals within 60 days of the EPA's order. 21 U.S.C. § 346a(h)(1).

NRDC filed administrative objections to the tolerances in 2002. The EPA published its Final Order denying those objections on August 10, 2005. Within 60 days, NRDC filed a petition for review in the Second Circuit, and NCAP filed a petition for review in this court. The Judicial Panel on Multidistrict Litigation transferred NRDC's petition for review to this court pursuant to 28 U.S.C. § 2112, and NRDC and NCAP filed joint briefs on appeal.

[3]NRDC did not request an evidentiary hearing on its objections.

STANDARD OF REVIEW

The FDCA does not establish a standard for reviewing pesticide tolerances that are established without a public evidentiary hearing. *See* 21 U.S.C. § 346a(h)(2). In the absence of such a standard, our review is governed by section 706 of the Administrative Procedure Act ("APA"). *See* 5 U.S.C. § 706; *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1205-06 (9th Cir. 2004).

Under the APA, we must set aside an agency's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency decision would normally be arbitrary and capricious if "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Mfrs' Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

"The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Id*. "Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.' " *Id.* (citation omitted). "In reviewing that explanation, [the court] must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (citation omitted).

Although we will "uphold a decision of less than ideal clarity if the agency's path may be reasonably discerned," we "may not supply a reasoned basis for the agency's action that the agency itself has not given." *Id.* (citations omitted).

ANALYSIS

Petitioners challenge seven tolerances (acetamiprid, fenhexamid, halosulfuron-methyl, isoxadifen-ethyl, mepiquat, pymetrozine, and zeta-cypermethrin) based on the EPA's failure to gather drinking water data as part of its exposure analysis. Petitioners also challenge three tolerances (acetamiprid, mepiquat, and pymetrozine) based on the absence of certain toxicity studies, and based on the EPA's failure to explain why it had reliable data in the absence of those toxicity studies.[4] We address these challenges in turn.

I.

[1] The FQPA directs the EPA to use an additional tenfold margin of safety to take into account completeness of data with respect to pesticide "*exposure* to infants and children." 21 U.S.C. § 346a(b)(2)(C) (emphasis added).

As required by the FQPA, the EPA monitors whether infants and children will be exposed to unsafe levels of pesticides in drinking water. However, the EPA lacks sufficient drinking water exposure data for several pesticides, including the ones at issue in this case. Therefore, the EPA used computer modeling to determine drinking water exposure for the seven pesticides. Because the modeling results revealed little-to-no risk of pesticide exposure in drinking water, the EPA reduced or removed the child safety factor for each of the pesticide tolerances.

Petitioners argue that because the EPA used modeling instead of actual sampling data to determine drinking water exposure to these pesticides, the EPA does not have "reliable

[4]Petitioners also initially challenged the tolerances for halosulfuron-methyl and zeta-cypermethrin on these grounds. They now acknowledge, however, that subsequent agency actions have rendered those challenges moot.

data" justifying its use of a lower than 10x margin of safety for the pesticide tolerances. *See* 21 U.S.C. § 346a(b)(2)(C). In short, Petitioners argue that modeling results can never constitute reliable data within the meaning of the FQPA.

[2] We disagree. Petitioners have presented no evidence that modeling does not yield reliable data. There is nothing inherently unreliable about the use of models in scientific assessments. *See, e.g.*, *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 535 (D.C. Cir. 1983) ("[A]dministrative agencies have undoubted power to use predictive models."). Moreover, because of the difficulty in sampling the entire nation's water supply, modeling is necessary to determine whether drinking water has been contaminated by pesticides. Topography, geology, and hydrology differ greatly across the nation and constantly change. In many cases, computer modeling can more accurately incorporate these elements and provide more reliable data than actual water sampling data can provide.[5]

[3] Therefore, we are unwilling to adopt the narrow construction of "reliable data" that Petitioners advance. Although the FQPA does not define "reliable data," we are confident that modeling results can satisfy this statutory requirement.

[4] Furthermore, in this case, the EPA provided a specific, detailed explanation of why its drinking water exposure models *do* yield reliable data. The Final Order states:

> *Lack of comprehensive drinking water (DW) monitoring data*. NRDC contends that, because EPA used a model for calculating drinking water expo-

[5]*See* FIFRA Scientific Advisory Panel, A Set of Scientific Issues Being Considered by the Agency in Connection with Estimating Drinking Water Exposure as a Component of Dietary Risk Assessment, 4-7 (Dec. 1997), *available at* http://epa.gov/scipoly/sap/meetings/1997/december/finaldec.pdf.

sure, EPA does not have, as a definitional matter, "reliable data" for choosing a factor different than the 10X default value. Similar comments were made during the development of EPA's Children's Safety Policy. This issue was addressed at length in the response to the imidacloprid objections. That response is incorporated herein and is summarized below.

Although the availability of drinking water monitoring data has increased dramatically in the last several years, EPA still finds it necessary to rely for most pesticides upon various exposure models to estimate exposure levels in drinking water. These models are based on generic data regarding fate and transport of pesticides in the environment, and they operate by combining this generic data with pesticide-specific data on chemical properties to estimate exposure. EPA has primarily used its drinking water models to "screen" those pesticides that may pose unacceptable risks due to exposures in drinking water from pesticides not likely to result in such exposures. To accomplish this goal, the models are based on data from studies at sites that are highly vulnerable to runoff of pesticides to surface water or leaching of pesticides to ground water. If a pesticide fails this conservative (health-protective) screen, EPA would investigate whether the model is significantly overstating the residue levels that actually occur.

EPA has developed models for estimating exposure in both surface water and ground water. EPA uses a two-tiered approach to modeling pesticide exposure in *surface water*. In the initial tier, EPA uses the FQPA Index Reservoir Screening Tool (FIRST) model. FIRST replaces the Generic Estimated Environmental Concentrations (GENEEC)

> model that was used as the first tier screen by EPA from 1995-1999. If the first tier model suggests that pesticide levels in water may be unacceptably high, a more refined model is used as a second tier assessment. The second tier model is actually a combination of the models, Pesticide Root Zone Model (PRZM) and the Exposure Analysis Model System (EXAMS). For estimating pesticide residues in *groundwater*, EPA uses the Screening Concentration In Ground Water (SCI-GROW) model. Currently, EPA has no second tier groundwater model.
>
> *Whether EPA assesses pesticide exposure in drinking water through monitoring data or modeling, EPA uses the higher of the two values from surface and ground water in assessing overall exposure to the pesticide. In most cases, pesticide residues in surface water are significantly higher than in ground water.*
>
> In the Imidacloprid Order, EPA analyzed each of its water models extensively. Based on the results of design characteristics of the models, outside peer review of the models, validation of the models, and comparison between the models' predictions and extensive water monitoring data, EPA concluded that the models are based on reliable data and will produce estimates that are unlikely to underestimate exposure to pesticides in drinking water.
>
> Accordingly, EPA reaffirms its earlier conclusion that its drinking water models provide a reliable basis for finding that exposure to pesticide residues in water are not underestimated.

Final Order at 46,726-29 (internal citations omitted) (emphasis added). Thus, the EPA addressed at length the reliability of its models. The EPA explained that the models yield con-

servative data because the models incorporate the higher of the two values from surface and ground water in assessing the overall risk of exposure to the pesticides. Petitioners have not established that the EPA's explanation regarding the reliability of its models is faulty or suspect.

[5] Accordingly, we conclude that the computer modeling used by the EPA to calculate the safety of drinking water was neither contrary to law nor arbitrary and capricious.[6] We affirm this aspect of the Final Order.

II.

In addition to NRDC's challenge to the completeness of exposure data, Petitioners also raise two arguments regarding whether reliable toxicity data supported a reduction in the child safety factor.

A.

NRDC first challenges the EPA's failure to wait for the results of certain developmental neurotoxicity studies ("DNT studies") before establishing tolerances for acetamiprid, mepiquat, and pymetrozine. The EPA specifically required the registrants of these pesticides to conduct DNT studies. However, the EPA did not wait for the results of the DNT studies before making its tolerance determinations.

[6]Our conclusion, of course, is not meant to suggest that the EPA's models are flawless. Petitioners have raised some concerns about the EPA's water exposure models that may warrant further scrutiny. To give one example, the EPA first performs a model-based water exposure test using conservative criteria; if the test results reveal *unacceptable* exposure levels, the EPA runs a second test to ensure that the first result was accurate. The EPA does not run a second test, however, if the initial test results reveal *acceptable* exposure levels. Although we are required to defer to the EPA's technical expertise in this area, *see, e.g.*, *Envtl Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 869 (9th Cir. 2003), we note that the EPA may wish to revisit this methodology.

Petitioners contend that DNT studies are essential for assessing pesticide effects. Petitioners explain that DNT studies are the best available studies for examining neurological effects in children because DNT studies are more sensitive than other studies, address areas that are not covered by other studies, and sometimes reveal developmental harm that is significant enough to require more stringent regulation. Petitioners argue that the EPA acted arbitrarily and capriciously by requesting DNT studies but failing to wait for the results of those studies before removing the child safety factor.

[6] Petitioners' position, however, is inconsistent with the Supreme Court's decision in *National Ass'n of Home Builders v. Defenders of Wildlife*, 127 S. Ct. 2518 (2007). In *Home Builders*, our court rejected a final order of the EPA as "arbitrary and capricious" because the EPA had relied on "legally contradictory positions" before arriving at its final administrative decision. 127 S. Ct. at 2529. The Supreme Court, however, reversed our opinion. The Court held that the mere fact that the EPA might have adopted "internally inconsistent" positions throughout the decision-making process did not render the EPA's final decision arbitrary and capricious. 127 S. Ct. at 2530. The Court explained that as long as agencies follow the proper administrative procedures, they have the authority to change their minds before issuing a final order. *Id.*

[7] Thus, *Home Builders* appears to foreclose Petitioners' argument. Even though the EPA initially thought that the DNT studies were needed, the EPA later determined that the DNT studies were not needed. Under *Home Builders*, the EPA's later determination does not *automatically* render the EPA's Final Order arbitrary and capricious. Notably, Petitioners have not identified any procedures that were violated when the EPA decided not to wait for the requested DNT studies before setting the tolerances. Moreover, the Final Order provided a reasoned explanation of why DNT studies are not actually required in every case where there is a reduc-

tion of the 10x child safety factor. Final Order at 46,711-12, 46,723-24.

[8] Therefore, we reject Petitioner's argument that the EPA acted arbitrarily and capriciously by establishing the pesticide tolerances for acetamiprid, mepiquat, and pymetrozine before receiving the DNT studies. While Petitioners' concerns about the EPA's apparent change of heart are understandable, on such questions of scientific judgment, we are required to defer to the EPA.

B.

[9] NRDC also disputes that the EPA's decision to deviate from the 10x presumptive child safety factor imposed by Congress was supported by reliable data establishing, with reasonable certainty, that the lower margin of safety for acetamiprid, mepiquat, and pymetrozine would not harm infants and children. 21 U.S.C. § 346a(b)(2)(A), (C). Even though the EPA was not necessarily required to wait for the results of the DNT studies, the decision to reduce the 10x child safety factor for these three pesticides must still be based on reliable data. Moreover, the EPA must tell the public why its data are reliable.

[10] The problem in this case is that the EPA's Final Order is vague, making it impossible for us to determine whether the EPA's deviations from the 10x child safety factor for acetamiprid, mepiquat, and pymetrozine were in fact supported by reliable data, even in the absence of the DNT studies. For example, with respect to pymetrozine, the Final Order states:

> NRDC challenged a December 27, 2001 action establishing tolerances for pymetrozine on cotton seed, cotton gin byproducts, the fruiting vegetables crop group, the cucurbit vegetables crop group, the leafy vegetables crop group (except Brassica), head and stem Brassica, leafy Brassica, turnip greens,

> dried hops, and pecans. (66 FR 66786, December 27, 2001). Given pymetrozine's exposure pattern and toxicological characteristics, EPA determined that pymetrozine potentially presented acute, chronic, short-term, and cancer risks and EPA quantitatively assessed these risks in making its safety determination. (66 FR at 66791-66792). All of these risks were found to be below the Agency's level of concern. (Id.). Although a DNT study was outstanding, EPA determined that the additional 10X children's safety factor could generally be reduced to 3X because the toxicological data showed no evidence of greater sensitivity to the young and there was no evidence of abnormalities in the development of the fetal nervous system. (64 FR 52438, 52444, September 29, 1999).

Final Order at 46,711.

The Final Order recites that the "toxicological data" showed no evidence of increased sensitivity for developing fetuses or the "young." However, the Final Order does not explain the connection between the toxicological data and the 3x margin of safety selected by the EPA in place of the 10x standard. This same critique applies to the Final Order's reasoning with respect to acetamiprid and mepiquat. As a result, it is entirely unclear why the EPA chose safety factors of 3x for pymetrozine and acetamiprid, and 1x for mepiquat, as opposed to 4x or 5x or 8x or 9x. As far as we can tell from the record, it appears that the EPA chose these lower safety levels arbitrarily—to acknowledge certain concerns about each pesticide, but with no specific evidence that these lower safety factors would actually account for the risks to infants and children.

[11] In sum, the Final Order does not provide enough information to demonstrate a rational connection between the factors that the EPA examined and the conclusions it reached.

See State Farm, 463 U.S. at 43. We are therefore unable to determine whether there was reliable data supporting the EPA's reductions of the 10x child safety factor. Although on remand the EPA may be able to explain why a 3x or 1x factor is appropriate, we cannot conclude it is appropriate on this record. To do so would abdicate our responsibility to ensure compliance with Congress's expressed desire to have a presumptive 10x child safety factor. Accordingly, we remand the tolerance regulations for acetamiprid, mepiquat, and pymetrozine to the EPA. *See, e.g.*, *State Farm*, 463 U.S. at 57 (remanding where the agency failed to supply the requisite "reasoned analysis"); *Safe Food & Fertilizer v. EPA*, 350 F.3d 1263, 1271 (D.C. Cir. 2003) (remanding for the EPA to provide "further explanation" of an exemption level for chromium found in zinc fertilizers).[7]

[7]While we are aware that the scope of our review under the APA is narrow, we are also mindful that we should not endorse the removal of the statutorily presumed child safety factor if we cannot determine that the EPA's conclusions are rationally supported. As Judge J. Skelly Wright of the D.C. Circuit elucidated, there is an important difference between the *depth* of our review of an agency's action and the *scope* of that review:

> Judicial review of agency action requires that the reviewing court consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. As noted by this court in *International Ladies Garment Workers Union v. Donovan*, 722 F.2d 795, 815 (D.C. Cir. 1983), *cert. denied*, 469 U.S. 820 (1984), such review "is not merely perfunctory. We are to engage in a 'searching and careful' inquiry, the keystone of which is to ensure that the [agency] engaged in reasoned decisionmaking."
>
> This formulation points to an acknowledged disparity between the depth of our review and the ultimate scope of that review: Although the ultimate scope may be narrow, the depth must be sufficient for us to be able to comprehend the agency's handling of the evidence cited or relied upon. The purpose of this in-depth review is to educate ourselves so that we can properly perform our reviewing function: determining whether the agency's conclusions are rationally supported. For, although data interpretation and analysis are functions that often lie within an agency's

The EPA and the dissent argue that Petitioners did not raise this argument below and therefore cannot assert it now. We disagree. In its administrative objections, NRDC challenged the basis for the reduced safety levels as inadequate. In particular, NRDC argued that, absent the DNT studies, the EPA had no reliable data to reduce the 10x child safety factor. NRDC's objection was a direct challenge to the lower child safety levels set by the EPA. To justify its decision to set a 3x or 1x child safety factor without the DNT studies, the EPA needed to explain why the data in its possession was reliable and supported such reductions. As noted above, the EPA explained why the absence of the DNT studies does not necessarily mean that there is a lack of reliable data justifying a downward deviation from the 10x child safety factor. However, the EPA failed to explain why, in the case of the three pesticides at issue, the available information justified the specific safety reductions. Because the NRDC challenged the EPA to provide that explanation, the EPA's failure to do so is properly before us for review.

CONCLUSION

Because the EPA failed to adequately explain the basis for its deviations from the 10x child safety factor for acetamiprid,

> realm of expertise, it is our duty to review those functions to ascertain whether the agency's actions were complete, reasoned, and adequately explained. The mere fact that an agency is operating in a field of its expertise does not excuse us from our customary review responsibilities. And, where the agency's reasoning, although complex, is rational, clear, and complete, we must affirm. Contrarily, where the agency's reasoning is irrational, unclear, or not supported by the data it purports to interpret, we must disapprove the agency's action.

Center for Auto Safety v. Peck, 751 F.2d 1336, 1373 (D.C. Cir. 1985) (Wright, J., dissenting) (internal citations and quotation marks omitted). *See also Riverkeeper, Inc. v. United States Environmental Protection Agency*, 475 F.3d 83, 103-04 (2d Cir. 2007) ("In a technical area of this sort, it is difficult for judges or interested parties to determine the propriety of the Agency's action without a justification for the action supported by clearly identified substantial evidence whose import is explained.").

mepiquat, and pymetrozine, we grant the petitions for review in part and remand to the EPA for further proceedings consistent with this opinion. On all other issues, we deny the petitions for review.

Each side to bear its own costs on appeal.

GRANTED IN PART, DENIED IN PART, AND REMANDED.

IKUTA, Circuit Judge, concurring in part and dissenting in part:

I agree with the majority's conclusion that "the computer modeling used by the EPA to calculate the safety of drinking water was neither contrary to law nor arbitrary and capricious." Maj. Op. at 13252; *see also The Lands Council v. McNair*, ___ F.3d ___, 2008 WL 2640001, at *6-10 (9th Cir. 2008) (en banc). I also agree with the majority's holding that *National Ass'n of Home Builders v. Defenders of Wildlife*, 127 S. Ct. 2518, 2529-30 (2007), forecloses petitioners' argument "that the EPA acted arbitrarily and capriciously by establishing the pesticide tolerances for acetamiprid, mepiquat, and pymetrozine before receiving . . . DNT studies." Maj. Op. at 13254.

I disagree, however, with the majority's conclusion that the tolerance regulations for acetamiprid, mepiquat, and pymetrozine must be remanded to the EPA because "it is entirely unclear why the EPA chose safety factors of 3x for pymetrozine and acetamiprid, and 1x for mepiquat," and therefore "the Final Order [did] not provide enough information to demonstrate a rational connection between the factors the EPA examined and the conclusions it reached." Maj. Op. at 13255. The petitioners failed to raise this argument in their objections to the EPA prior to the issuance of the Final Rule.

See Order Denying Objections to Issuances of Tolerances, 70 Fed. Reg. 46,706 (Aug. 10, 2005) [hereinafter, Final Rule], and therefore the EPA was given no opportunity to explain its rationale for adopting the 3x and 1x safety factors. Because we may review only the objections raised before the EPA, *see* 21 U.S.C. § 346a(g)-(h); 40 C.F.R. §§ 178.25(a)(2), 180.30(b), the issue is not properly before us. Even if the petitioners had raised this objection, there is no doubt the EPA could have provided information sufficient to demonstrate a rational basis for selecting these safety factors. Indeed, the record establishes that the EPA drew upon its expertise to select uncertainty factors based on principles well established in the scientific community. There is no basis for the majority's conclusion that the agency's path is not reasonably discernable in this case. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Accordingly, I dissent from Part IIB of the majority opinion.[1]

A

As noted by the majority, the tolerance rules at issue in this appeal have substantially similar histories.[2] While the development of its safety factor policy was in process, the EPA received pesticide petitions requesting the issuance of toler-

[1]I also dissent from footnote 6 of the majority opinion. The majority's suggestion that the "EPA may wish to revisit [its] methodology" regarding its "model-based water exposure test[s]" conflicts directly with the teaching of our en banc panel in *Lands Council*. *Lands Council* emphasized that it "is not a proper role for a federal appellate court" to "act as a panel of scientists that instructs the [agency] how to validate its hypotheses," "chooses among scientific studies," and requires the agency to "explain every possible scientific uncertainty." 2008 WL 2640001, at *4. The majority errs in this case by doing that which *Lands Council* expressly forbids.

[2]The three pesticides at issue are acetamiprid, mepiquat, and pymetrozine. For the individual tolerance rulings, see Acetamiprid; Pesticide Tolerance, 67 Fed. Reg. 14,649 (Mar. 27, 2002); Mepiquat; Pesticide Tolerance, 67 Fed. Reg. 3,113 (Jan. 23, 2002); Pymetrozine; Pesticide Tolerance, 66 Fed. Reg. 66,786 (Dec. 27, 2001).

ances under the FFDCA for the three pesticides at issue. As required in the FFDCA, the EPA reviewed the scientific data and other information, evaluated their completeness and reliability, and considered "the relationship of the results of such studies to human risk." 21 U.S.C. § 346a(b)(2)(D)(iii); *see, e.g.*, Pymetrozine; Pesticide Tolerance, 66 Fed. Reg. 66,786, 66,787 (Dec. 27, 2001). The EPA determined that the child safety factor was not necessary, or could be reduced to 3x, for each of the pesticides based on its analysis of potential exposure levels for the given pesticide, the extent to which the pesticide affected fetal development, and the effects, if any, on infants as observed in multi-generational studies of mammals. In each case, the EPA provided a reasoned explanation for eliminating or reducing the child safety factor.[3]

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[3]In its order establishing the tolerance for acetamiprid, the EPA explained:

> [T]he safety factor could be reduced to 3x for acetamiprid because the toxicology database is complete; there is no quantitative or qualitative evidence of increased susceptibility following in utero exposure of rat and rabbit fetuses; the dietary (food and water) and residential exposure assessments will not underestimate the potential exposures for infants, children, and/or women of childbearing age; and the requirement of a developmental neurotoxicity study is not based on criteria reflecting special concern for the developing fetuses or young which are generally used for requiring a DNT study and a safety factor.

Acetamiprid; Pesticide Tolerance, 67 Fed. Reg. at 14,655.

The EPA removed the additional child safety factor for mepiquat (reducing it to 1x) because it had already satisfied itself of the safety of another "salt" of mepiquat that it determined was identical in terms of its environmental distribution and toxicology. Mepiquat; Pesticide Tolerance, 67 Fed. Reg. at 3,115-16. It explained:

> The Agency published a risk assessment for mepiquat chloride on January 12, 2000, that discusses use on cotton as well as all other registered uses of mepiquat chloride. In that analysis risk estimates for exposure to mepiquat chloride were below the Agency's level of concern. The Agency has reviewed a dissociation study for mepiquat pentaborate that demonstrates that mepiquat pentaborate dissociates in an identical physical manner to

In 2002, the NRDC filed objections to the final rules for each of the pesticides based on the EPA's decision to reduce the 10x safety factor to 3x or 1x. The NRDC's objections were based on the theory that the EPA did not have "reliable data" which would allow it to reduce the child safety factor because the EPA had not yet received the results of a DNT study for each pesticide, and because the EPA relied on drinking water exposure models rather than on pesticide-specific

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> mepiquat chloride in water. Therefore, the analysis performed for mepiquat chloride or the "chloride salt," also pertains to this mepiquat "pentaborate salt" use because the use rate, maximum seasonal use rate and other pertinent use factors remain the same for mepiquat chloride or the "chloride salt." . . .
>
> Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.
>
> The Agency has determined that the FQPA safety factor for mepiquat is 1X. See the Agency's risk assessment for mepiquat chloride dated January 12, 2000, for details. The facts are that mepiquat pentaborate is another "salt" of mepiquat and that mepiquat pentaborate disassociates to mepiquat and therefore the basic toxicology data base for mepiquat chloride pertains to mepiquat pentaborate.

Id.

In establishing the tolerance for pymetrozine, the EPA stated:

> There is a complete toxicity database for pymetrozine and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children could be reduced to 3. The FQPA factor is reduced after assessing the potential for additional sensitivity of infants and children to residues of pymetrozine in the following studies: developmental toxicity studies in rabbit and rat and two-generation reproduction study in the rat. There was no evidence of increased susceptibility in these studies. The FQPA safety factor was not reduced to one due to the need for a developmental neurotoxicity study.

Pymetrozine; Pesticide Tolerance, 66 Fed. Reg. at 66,791.

drinking water monitoring data.[4] Notably, the NRDC did not object on the ground that the EPA failed to justify its choice of a safety factor of 3x or 1x relative to some other safety factor, such as "4x or 5x or 8x or 9x." Maj. Op. at 13255.[5] The EPA rejected NRDC's objections in the Final Rule, and provided a detailed explanation of its basis for concluding that it had reliable data notwithstanding the absence of certain DNT studies and the use of exposure models, and why such reliable data supported the EPA's conclusion that it could safely reduce the child safety factor. *See generally* 70 Fed. Reg. 46,706. The Final Rule upheld the 3x child safety factor for acetamiprid and pymetrozine, and the 1x child safety factor for mepiquat. *Id.* at 46,711-13, 46,736.

B

In concluding that remand is required because the EPA failed to explain why it chose a 3x uncertainty factor for acetamiprid and pymetrozine and a 1x uncertainty factor for mepiquat instead of "4x or 5x or 8x or 9x," Maj. Op. at

[4]Natural Resources Defense Council, *Objections to the Establishment of Tolerances for Pesticide Chemical Residues: Halosulfuron-methyl and Pymetrozine Tolerances* (filed Feb. 25, 2002); Natural Resources Defense Council, *Objections to the Establishment of Tolerances for Pesticide Chemical Residues: Imidacloprid, Mepiquat, Bifenazate, Zeta-cypermethrin, and Diflubenzuron Tolerances* (filed May 19, 2002); Natural Resources Defense Council, *Objections to the Establishment of Tolerances for Pesticide Chemical Residues*: *Isoxadifen-ethyl, Acetamiprid, Propiconazole, Furilazole, Fenhexamid, and Fluazinam Tolerances* (filed May 20, 2002).

[5]The NRDC also objected to the three tolerances on a number of other grounds, including the failure to consider farm children adequately, a failure to consider worker risk adequately, an inadequate aggregate risk assessment, an improper reliance on a "lowest observed adverse effect level" (LOAEL) rather than a "no observed adverse effect level" (NOAEL), a residue "percentile" assumption that inadequately protected infants and children, and an improper assessment of chronic dietary exposure, among others. The NRDC did not raise these issues to us on appeal. *See supra* Note 4; Final Rule, 70 Fed. Reg. at 46,713-14, 46,717-36.

13255, the majority is reaching an argument not properly before us. The regulations applicable to the FFDCA require exhaustion of administrative remedies. *See* 40 C.F.R. § 180.30(b) (providing that "judicial review is not available unless an adversely affected party exhausts the[ ] objection procedures, and any petition procedures preliminary thereto"). In order to exhaust the objection procedure provided by the FFDCA, petitioners must raise their objections to the agency with specificity. *See* 21 U.S.C. § 346a(g)(2)(A) (requiring objections to an EPA order establishing a tolerance to specify "with particularity the provisions of the regulation or order deemed objectionable"); 40 C.F.R. § 178.25(a)(2) ("To be considered by the Administrator, an objection must: Specify with particularity the provision(s) of the order, regulation, or denial objected to, the basis for the objection(s), and the relief sought."). The purpose of this administrative exhaustion requirement is to give notice to an agency of specific errors or issues, so the agency can "bring the Agency's experience to bear on a contested question," *Nader v. EPA*, 859 F.2d 747, 754 (9th Cir. 1988), and either correct the error or provide a reasoned explanation.

The NRDC objected to the EPA's decision that a 10x safety factor was not required for each of the three pesticide tolerances, and based this objection on the ground that the EPA lacked reliable data because it had failed to obtain a DNT study and had relied on drinking water exposure models. The majority rests its decision that the tolerances for acetamiprid, mepiquat, and pymetrozine must be remanded to the EPA on a different ground, namely that the EPA failed to explain why it chose a 3x uncertainty factor for acetamiprid and pymetrozine and a 1x uncertainty factor for mepiquat instead of "4x or 5x or 8x or 9x," Maj. Op. at 13255. Because the NRDC did not object to the EPA's decision on the ground that the EPA had failed to give a clear explanation of the 3x or 1x safety factor in lieu of "4x or 5x or 8x or 9x," *id.*, the issue identified by the majority is not exhausted, and we are precluded from reviewing it.

The majority attempts to justify addressing issues that the NRDC did not raise to the EPA by turning the administrative exhaustion requirement on its head. As noted above, under the regulations requiring exhaustion of administrative remedies, parties objecting to proposed regulations bear the initial burden, and must raise their specific objections to the agency; any issues not raised are waived and need not be considered by the agency or by the court on appeal. 40 C.F.R. §§ 178.25(a)(2), 180.30. Here, the majority shifts the burden to the EPA to identify, raise, and resolve additional issues that petitioners failed to raise at all, let alone frame with the requisite "particularity." *Id.* § 178.25(a)(2).

The majority first notes that "the NRDC argued that, absent the DNT studies, the EPA had no reliable data to reduce the 10x child safety factor." Maj. Op. at 13257. This is indeed the specific objection raised by the NRDC. The majority then recharacterizes this specific objection as being a more general "challenge to the lower child safety levels set by the EPA." Maj. Op. at 13257.[6] From this generalization, the majority leaps to the conclusion that the NRDC's specific objection places a burden on the EPA to "explain why the data in its possession" supported its decision to set a 3x or 1x child safety factor for the pesticides at issue "as opposed to 4x or 5x or 8x or 9x." Maj. Op at 13255, 13257. There is no basis in our case law for taking such a leap or placing such a burden on the EPA. We have never required an agency to interpret a specific objection as being, at some level of generality, a different, broader objection, and responding to that different objection. *See, e.g., High Country Resources v. FERC*, 255 F.3d 741, 745-46 (9th Cir. 2001) (stating that a petitioner cannot "implicitly" raise an issue to a regulatory agency in order to exhaust administrative remedies, but must provide "much

[6]As noted *supra*, however, a valid objection cannot be this general; it must "[s]pecify with particularity the provision(s) of the order, regulation or denial objected to, the basis for the objection(s), and the relief sought." 40 C.F.R. § 178.25.

more specificity in the statement of objection" and present the issue "squarely" to the agency.). Nor would it be reasonable or consistent with the purpose of the administrative exhaustion requirement to do so. Here, the EPA responded to the NRDC's specific objection by carefully explaining why the absence of DNT studies did not require the retention of the 10x safety factor. The EPA satisfied its burden, and had no additional obligation to make a further response.

In short, we have no authority to reverse an agency decision based on an objection that was not raised. The Supreme Court has long warned us not to invent new issues as part of our review of objections raised to an administrative agency. "A reviewing court usurps the agency's function when it sets aside the administrative determination upon a ground not theretofore presented and deprives the [administrative agency] of an opportunity to consider the matter, make its ruling, and state the reasons for its action." *Unemployment Comp. Com'n v. Aragon*, 329 U.S. 143, 155 (1946); *see also Woodford v. Ngo*, 548 U.S. 81, 89 (2006). The EPA addressed, with adequate thoroughness and detail, *see, e.g.*, *Balt. Gas and Elec. Co.*, 462 U.S. at 105-06, each of the objections filed by the NRDC. These objections create the compass of our limited review. 21 U.S.C. § 346a(h)(1), (5); 40 C.F.R. § 178.25(a)(2).[7]

(Text continued on page 13267)

[7]The majority also relies in part upon the dissent of Judge Wright in *Center for Auto Safety v. Peck*, 751 F.2d 1336, 1373 (D.C. Cir. 1985) (Wright, J., dissenting). Maj. Op. at 13256-57 n.7. However, Judge (now Justice) Scalia's opinion for the majority in that case captures the dissent's error, and, concomitantly, the majority's mistake in this case when it warns that "we must be implacably skeptical of belated recognition at the appellate stage that elements of scientific analysis unchallenged during a contested proceeding are incomprehensible without further explanation. To credit such post-appeal pleas of inadequate information is to threaten the integrity of all rulemaking in fields beyond our own limited scientific ken." *Id.* at 1361. The entirety of the passage bears repeating:

> The dissent's response is equally unsatisfactory, consisting essentially of the assertion that late presentation of the issue must be disregarded because validity of the [data] curves is essential to

validity of the agency's conclusion. It is simply not the case, however, that all of the essential postulates for an agency rule must be contained in the record. Every judgment of any consequence is constructed upon an infinitude of other judgments, of greater or lesser certitude, in a progression of logical dependency terminating in a first principle the equivalent of 1 + 1 = 2. They cannot all possibly be included in the statement of basis and purpose for a rulemaking. We do not have authority to require that all elements underlying a rule be set forth in a fashion "understandable to a layman," *see Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 557, 98 S. Ct. 1197, 1218, 55 L. Ed. 2d 460 (1978). And it may as well be disclosed that in scientific fields we judges ourselves are laymen, ill equipped to determine where the line falls between requisite explanation of problematic analysis and useless replication of what for the cognoscenti amounts to a textbook on basic physics. Thus, our "feel" for the adequacy of an analysis in such cases is necessarily governed by the reaction that it elicits from knowledgeable commenters. From the point at which it reaches common ground we can reasonably assume that no further explication is required. We will hear on appeal assertions that needful elaborations fairly requested were not provided; but we must be implacably skeptical of belated recognition at the appellate stage that elements of scientific analysis unchallenged during a contested proceeding are incomprehensible without further explanation. To credit such post-appeal pleas of inadequate information is to threaten the integrity of all rulemaking in fields beyond our own limited scientific ken. The present challenge to the effectiveness curves presents the threat in a particularly flagrant form. NHTSA *specifically asked* the petitioners (and other rulemaking participants) in 1979: "Do the existing analyses represent the most appropriate methods of approaching a study of bumper standards at different impact speeds and levels of damage resistance? If not, what method should be used?" Though State Farm and IIHS, among others, responded with substantial comments there was not even a suggestion that the effectiveness curves represented a fundamentally invalid methodology. The dissent provides a list of reasons why petitioners might not have raised these objections during the rulemaking proceeding, Dissent at 1387-88 all of which boil down to petitioners' probable reluctance to upset favorable determinations. Even if that were the

C

Even were it proper for us to address the adequacy of the EPA's consideration of an issue not raised, the record provides an adequate basis for us to conclude that the EPA's selection of a 3x and 1x uncertainty factor was not arbitrary, as the majority erroneously concludes. Maj. Op. at 13255.

The record in this case contains the EPA's published guidance for determination of an appropriate FQPA safety factor. *See* Office of Pesticide Programs, EPA, *Determination of the*

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only consideration, it would be of questionable wisdom to reward their tactical decision to leave the agency in the dark—and thus encourage benighted agency action in the future. But in any event, the dissent's speculations do not explain why the *proponents* of the 2.5 mph standard did not raise these arguments. In fact, some commenters on the June 1979 Final Assessment (which supported the 5.0 mph standard) did object that the "effectiveness ratios for *5.0 mph* systems are overstated to a considerable extent," but that objection was based upon the lack of correspondence with repair cost data rather than theoretical inadequacy of the effectiveness curves.

We conclude that the curves were considered part of the common ground of expert analysis that required no further explanation. Petitioners' objections on this score put us in mind of the Supreme Court's injunction in *Vermont Yankee* that administrative proceedings should not be a game or a forum to engage in unjustified obstructionism by making cryptic and obscure reference to matters that "ought to be" considered and then, after failing to do more to bring the matter to the agency's attention, seeking to have that agency determination vacated on the ground that the agency failed to consider matters "forcefully presented."

435 U.S. at 553-54, 98 S. Ct. at 1217. These instructions are even more appropriate when cryptic and obscure reference to theoretical inadequacy—or in fact, even less than that, mere assertion of lack of explanation of theoretical adequacy—is first made on appeal.

Id. at 1361-62 (emphases in original, internal citations to the record omitted).

Appropriate FQPA Safety Factor(s) in Tolerance Assessment 10 (Feb. 28, 2002). As explained in this guidance document, "when evaluating whether reliable data are available to support a FQPA safety factor different from the default 10x FQPA safety factor and what level of 'different' FQPA safety factor would be safe for infants and children," *id.* at 19, the EPA may, in the exercise of its scientific judgment, consider the 3x uncertainty factor that has traditionally been used for evaluating risks posed by pesticide exposure in a related context. *See id.* at 26; *see also id.* at 9-10 (noting that in evaluating the risks posed by pesticide exposure, "often a value of 3x is used to address database deficiencies . . . ."). However, in "the optimal case" in "which there is a high level of confidence that the hazard and exposure assessments are sufficiently conservative[,] and there are no residual uncertainties in the assessment," the EPA will remove the safety factor, *i.e.*, it will apply a "safety factor of 1X," deeming the existing threshold "sufficient to protect infants and children." *Id.* at 51-52. *See also* Office of Pesticide Programs, EPA, *Office of Pesticide Programs' Policy on The Determination of The Appropriate FQPA Safety Factor(s) For Use in The Tolerance-setting Process: Response to Public Comments OPP Docket OPP-00610* 97 (Feb. 28, 2002) (internal citation omitted) (further explaining the long-standing basis for "imposing a database uncertainty factor of 3X if one key study is missing from the database and a factor of 10X if more than one is missing.").

Other EPA tolerance-setting regulations reflect the approach described in its guidance documents for selecting a FQPA safety factor different from the default 10x FQPA safety factor. *See, e.g.*, Fenarimol; Pesticide Tolerance, 71 Fed. Reg. 32,841, 32,844-45 (June 7, 2006) (noting that the EPA originally reduced the FQPA Safety factor from 10x to 3x subject to receiving additional data, and subsequently recommended reducing the 3x FQPA Safety factor to 1x when it obtained adequate data); Thiacloprid; Pesticide Tolerances, 68 Fed. Reg. 55,503, 55,509 (Sept. 26, 2003) ("Although the

lack of morphometric assessments in the DNT raised some uncertainty, EPA determined that there were sufficient reliable data to select an additional safety factor of 3X instead of 10X."). The EPA relied on this long-established approach in setting the safety factors for the three pesticides at issue here, *see supra* at nn.2 & 3.

Because the petitioners did not challenge the absence of an explanation as to why the EPA picked a 3x or 1x factor rather than a "4x or 5x or 8x or 9x" factor, we are deprived of the EPA's more detailed explanation as to why the scientific community relies on the 3x uncertainty factor when database deficiencies are identified. Nevertheless, the record indicates that use of the 3x uncertainty factor is generally accepted by the scientific community. *See* Michael L. Dourson et al., *Evolution of Science-Based Uncertainty Factors in Noncancer Risk Assessment*, 24 Regulatory Toxicology and Pharmacology 108 (1996) (generally discussing the science underlying the use of 10x and 3x default uncertainty factors). Indeed, the lack of any controversy regarding the rationale underlying the selection of a 3x safety factor rather than a "4x or 5x or 8x or 9x" factor may explain why the NRDC did not argue in its objections to the EPA that the agency needed a special justification for selecting a 3x safety factor, once the EPA determined that the additional 10x factor was not required. In light of the EPA's reliance on a long-established and widely accepted protocol, the majority's statement that "the EPA chose these lower safety levels arbitrarily" is not supported by the record, and is contrary to our obligation to defer to the scientific analysis and judgments made by an agency operating within its area of special expertise. *Balt. Gas and Elec. Co.*, 462 U.S. at 103.

As we have recently emphasized, "[w]e are to be most deferential when the agency is making predictions, within its area of special expertise, at the frontiers of science." *Lands Council*, 2008 WL 2640001, at *9 (internal quotation marks and alterations omitted). *Lands Council* prohibits us from indulg-

ing the temptation to "act as a panel of scientists." *Id.* at *4. Nor can we require the agency "to always demonstrate the reliability of its scientific methodology or the hypotheses underlying the [agency's] methodology." *Id.* at *7 (internal quotation marks omitted). *Lands Council* teaches that our proper role is simply to ensure that the agency, in its expertise, made no clear error of judgment rendering its action arbitrary and capricious. *See id.* at *9-10. The EPA's choices in this case were neither arbitrary nor capricious and we must defer to its judgment. *See* 5 U.S.C. § 706(2)(A); *Balt. Gas and Elec. Co.*, 462 U.S. at 103-05. Accordingly, I would deny the petition for review in its entirety.