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No. 10-1031

In the Supreme Court of the United States

NATIONAL CORN GROWERS ASSOCIATION, ET AL.,
PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the Environmental Protection Agency reasonably determined that it was not "necessary" (21 U.S.C. 346a(g)(2)(B)) to conduct an evidentiary hearing concerning the safety risk posed by a particular pesticide, after the agency concluded that petitioners' submissions in support of a hearing did not comply with the agency's procedural rules and did not create a genuine issue of material fact.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-15a) is reported at 613 F.3d 266. The orders of the Environmental Protection Agency (Pet. App. 16a-342a, 343a-368a, 369a-376a) are reported at 74 Fed. Reg. 59,608 (2009), 74 Fed. Reg. 23,046 (2009), and 73 Fed. Reg. 44,864 (2008).

JURISDICTION

The judgment of the court of appeals was entered on July 23, 2010. A petition for rehearing was denied on October 19, 2010 (Pet. App. 381a). On December 28, 2010, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including February 16, 2011, and the petition was filed on that

date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. The Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, directs the Environmental Protection Agency (EPA) to ensure that pesticide residues on foods distributed to American consumers are safe. See generally 21 U.S.C. 346a (2006 & Supp. III 2009). The FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue," including exposures through drinking water. 21 U.S.C. 346a(b)(2)(A)(ii).

The FFDCA requires EPA to establish "tolerances"—the maximum level of a pesticide residue allowed in or on food. 21 U.S.C. 346a (2006 & Supp. III 2009). Without a tolerance (or an exemption), food containing pesticide residues is considered unsafe and thus "adulterated," meaning that it cannot be legally distributed in interstate commerce. 21 U.S.C. 342(a); see 21 U.S.C. 331(a) (Supp. III 2009). EPA must revoke or modify a tolerance if the agency determines it is not "safe." 21 U.S.C. 346a(b)(2)(A)(i). In deciding whether to revoke a tolerance, EPA must separately evaluate the risk a pesticide poses to infants and children, by considering, *inter alia*, "the special susceptibility of infants and children to the pesticide chemical residues" and "the cumulative effects on infants and children of such residues." 21 U.S.C. 346a(b)(2)(C)(i)(II) & (III).

The statute establishes a multi-step process for the revocation of a tolerance. 21 U.S.C. 346a(e)-(g). EPA must first publish a proposed revocation rule and generally must provide a 60-day public comment period. 21 U.S.C. 346a(e)(2). After considering comments sub-

mitted during that period, EPA issues a final rule. 21 U.S.C. 346a(e)(1)(A).

After the agency has issued a final rule, any person may file objections with EPA "specifying with particularity the provisions of the regulation or order deemed objectionable" and may request an evidentiary hearing on those objections. 21 U.S.C. 346a(g)(2). The FFDCA states that EPA shall "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." 21 U.S.C. 346a(g)(2)(B).

EPA regulations state that the agency will hold a hearing only if it "determines" that the material submitted by the requestor shows that (1) there is "a genuine and substantial issue of fact" for resolution at a hearing; (2) there is "a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor" of the requesting party; and (3) the resolution of the factual issues in the manner sought by the requesting party "would be adequate to justify the action requested." 40 C.F.R. 178.32(b). If a person files objections, EPA must issue a final order separately stating the action taken on each objection and whether any hearing is appropriate. 21 U.S.C. 346a(g)(2)(C).

b. EPA also regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires EPA approval of pesticides prior to their sale and distribution, and it establishes a registration regime that regulates the use of pesticides. 7 U.S.C. 136a(a). FIFRA also requires EPA to review

and approve pesticide labels, and it provides that use of a pesticide inconsistent with its label is illegal. 7 U.S.C. 136j(a)(2)(G).

2. EPA has classified the pesticide carbofuran as "Toxicity Category I, the most toxic category, based on its potency by the oral and inhalation exposure routes." *Carbofuran; Final Tolerance Revocations*, 74 Fed. Reg. 23,046, 23,071 (2009) (*Final Rule*). Carbofuran causes inhibition of the enzyme acetylcholinesterase, and such inhibition can result in "prolonged stimulation of nerves and muscles." *Ibid.* Among the symptoms of carbofuran poisoning are "headache, nausea, dizziness, blurred vision, excessive perspiration, salivation, lacrimation (tearing), vomiting, diarrhea, aching muscles, and a general feeling of severe malaise." *Ibid.* "Severe poisoning can lead to convulsions, coma, pulmonary edema, muscle paralysis, and death by asphyxiation." *Ibid.* Carbofuran poisoning can also lead to neurological and psychological symptoms, such as "confusion, anxiety, depression, irritability, mood swings, difficulty concentrating, short-term memory loss, persistent fatigue, and blurred vision." *Ibid.* Carbofuran has a "steep dose-response curve," meaning that "small differences in human exposure levels can have significant adverse consequences for large numbers of individuals." *Ibid.*

a. In 2006, EPA completed a dietary risk assessment for carbofuran that "showed acute dietary risks from carbofuran residues in food above EPA's level of concern." *Final Rule*, 74 Fed. Reg. at 23,048-23,049. In May 2008, petitioner FMC Corporation (FMC), which markets carbofuran, offered to modify its registration to "cancel" all use of the chemical on certain crops. Under the proposed modification, FMC would have adopted use restrictions to "mitigate" water contamination on re-

maining uses, in exchange for EPA's agreement to "permit the retention of several uses that do not meet the FFDCA * * * safety standard or the FIFRA registration standard." *Carbofuran; Proposed Tolerance Revocations*, 73 Fed. Reg. 44,864, 44,866 (2008) (*Proposed Rule*). EPA declined the offer, and FMC withdrew it. *Ibid.*

On July 31, 2008, EPA proposed to revoke all tolerances for carbofuran on the ground that aggregate exposures from all uses of carbofuran are not "safe." *Proposed Rule*, 73 Fed. Reg. at 44,864; see *id.* at 44,866 ("[U]nder every analysis EPA has conducted, the levels of carbofuran exceed the safe daily dose for children, even when EPA used the most refined data and models available. Based on these findings, EPA has decided to move as expeditiously as possible to address the unacceptable dietary risk to children."). The *Proposed Rule* advised parties that if they "anticipate[d] that [they] may wish to file objections to the final rule, [they] must raise those issues in [their] comments on this proposal." *Id.* at 44,865; see *id.* at 44,864 ("Issues not raised during the comment period may not be raised as objections to the final rule, or in any other challenge to the final rule."). EPA emphasized that it would "treat as waived, any issue not originally raised in comments on this proposal." *Id.* at 44,865.

b. On September 29, 2008 (the date comments were due on the proposed tolerance revocation), FMC asked EPA to cancel carbofuran's registration under FIFRA for 28 crops. *Final Rule*, 74 Fed. Reg. at 23,047. At the same time, FMC "indicated that it no longer seeks to maintain the tolerances associated with the domestic use of carbofuran on the eliminated crops, and therefore no

longer opposes the revocation of those tolerances." *Ibid.* EPA accordingly revoked the tolerances. *Ibid.*

At the same time, FMC sought to retain EPA tolerances for two "national food uses," corn and sunflowers, and "two regional food uses," potatoes in the Northwest and pumpkins in the Southeast. *Final Rule*, 74 Fed. Reg. at 23,060. EPA concluded, however, that continued use of the chemical even in that limited manner was not safe because its "analyses show that those individuals—both adults and children—who receive their drinking water from sources vulnerable to carbofuran contamination are exposed to carbofuran levels that exceed EPA's level of concern—in some cases by orders of magnitude." *Id.* at 23,047; see *ibid.* (explaining that "estimates for aggregate food and ground water exposure" ranged from 780% of the safe dose for adults over age 50 to 9400% of the safe dose for infants); see also *id.* at 23,060.

FMC had submitted "assessments that relied in part on what [it] refer[ed] to as 'county-level usage data'" in an effort to have EPA's exposure model replace its assumption of 100% use of carbofuran in cropped areas with a much lower figure. *Final Rule*, 74 Fed. Reg. at 23,066; see *id.* at 23,065. EPA "agree[d] [with FMC] that county-level use data would be useful in generating reasonable estimates of [the percentage of crops treated (PCT)] that could be used in drinking water assessments." *Id.* at 23,066. The agency found, however, that the material FMC had provided was unreliable for two independent reasons.

First, rather than providing actual "usage data," FMC had provided "estimates" that the company apparently had derived from sales data. *Final Rule*, 74 Fed. Reg. at 23,066. FMC declined, however, to provide the "'actual sales data' [it] used to develop these estimates,

or the methods used to estimate county level usage from the sales data." *Ibid.* "In the absence of the data or [such] analyses * * *, EPA [was] unable to verify or evaluate the results of any analyses that rely on these data and [could] reach no conclusion on its validity or utility." *Ibid.*

Second, FMC's methodology (to the extent EPA could discern it from the company's incomplete submissions) did not "appear to account for uncertainties due to variation in time and space and the potential for use to be locally concentrated due to pest pressures." *Final Rule*, 74 Fed. Reg. at 23,066. EPA explained that, because "pesticide use varies from year to year, and can in some cases be patchy, with high levels of use in small areas and little use in most areas," FMC's methodology could result in "substantial" underestimation of the percentage of crops treated in "small watersheds." *Ibid.*

Notwithstanding the inadequacy of FMC's data, EPA performed a "sensitivity analysis" to determine whether lowering the assumed percentage of crops treated below 10% would "meaningfully affect the outcome of the risk assessment." *Final Rule*, 74 Fed. Reg. at 23,068. The agency concluded that "use of a reasonably conservative [percentage of crops treated] estimate, even if one could be developed, would not meaningfully affect the carbofuran risk assessment, as aggregate exposures would still exceed 100%" of the safe daily dose. *Ibid.*; see *id.* at 23,084.

As part of their comments, petitioners also "summariz[ed] * * * the results" of a "national leaching assessment" that "they claim[ed] to have conducted" regarding the soil and water conditions that would and would not lead to carbofuran contamination of ground water. *Final Rule*, 74 Fed. Reg. at 23,060. Petitioners

did not, however, submit the assessment itself. *Ibid.* EPA therefore was unable to evaluate the assessment's "methodology" or "whether the assessment actually support[ed] [petitioners'] claims." *Id.* at 23,061 ("Based on the information provided, EPA cannot confirm or negate the assertion that there is no overlap between use and all potentially vulnerable ground water, as the information provided does not enable the Agency to evaluate this claim."); *id.* at 23,062 (EPA unable to "determine model input parameters or check model algorithms" based on limited information provided by petitioners).

EPA advised interested parties that they could file objections to the *Final Rule*, while stating (as it had in the *Proposed Rule*) that "the substance of the objection must have been initially raised as an issue in comments on the proposed rule." *Final Rule*, 74 Fed. Reg. at 23,047; see *Proposed Rule*, 73 Fed. Reg. at 44,864, 44,865. Accordingly, EPA warned parties that it "[would] treat as waived any issue not originally raised in timely submitted comments." *Final Rule*, 74 Fed. Reg. at 23,047.

c. On June 29, 2009, FMC proposed yet again to amend carbofuran's FIFRA registration, this time to adopt, *inter alia*, a novel scheme relying on post-application monitoring by FMC of pesticide usage in an attempt to limit carbofuran usage to two percent of a watershed. Pet. App. 112a. FMC also proposed geographic restrictions on carbofuran's use, additional crop restrictions, and set-back requirements. *Id.* at 113a. On the same day, petitioners filed objections to the *Final Rule* and requested an evidentiary hearing. *Id.* at 21a. Petitioners' objections were "based on the FIFRA registration amendments that FMC filed" simultaneously

with its comments, *i.e.*, "45 days after the safety determination was made." *Id.* at 22a; see *id.* at 78a (explaining that petitioners' objections were "inextricably intertwined with proposed changes to carbofuran's FIFRA registration that were not submitted until after publication of the final tolerance revocation rule").

On November 18, 2009, EPA denied Petitioners' objections and hearing requests on several independent grounds. Pet. App. 16a-342a. First, EPA determined that, under settled administrative procedure, petitioners could not "challeng[e] EPA's safety determination based on proposed FIFRA registration changes not before EPA at the time of its final revocation decision." *Id.* at 22a. EPA noted that FMC was free to continue its pursuit of the proposed FIFRA registration amendments and then, if EPA accepted them, request the reestablishment of carbofuran tolerances based on the new registration. *Id.* at 22a-23a; see *id.* at 86a. The agency explained, however, that FMC could not require EPA to "shoot at a moving target, much less a target that is not in existence," by proposing to limit the pesticide's adverse impact only after EPA had made its final determination. *Id.* at 85a ("Petitioners are actually not objecting to the conclusions in the EPA's final rule; rather, they are suggesting that EPA might reach a different result in a different factual scenario."); see *id.* at 78a, 114a-115a; 310a-311a.

EPA further concluded that, even aside from the inappropriate use of the untimely registration proposal, petitioners had not properly joined issue with the conclusions the agency had announced in the *Final Rule*. Pet. App. 23a. Petitioners had repeatedly failed to respond to the agency's "detailed determinations" in the *Final Rule*, instead merely filing "recycled comments on

the proposed rule." *Id.* at 23a-24a. The *Final Rule* had responded to the points made in the earlier comments, yet petitioners had simply refiled those comments without attempting to articulate how the agency had erred in its responses. *Id.* at 23a; see *id.* at 73a, 78a-79a, 312a.

Petitioners had also repeatedly attempted to rely on untimely-filed submissions and had failed to submit supporting documents that would have allowed the agency to evaluate petitioners' empirical claims. Pet. App. 23a. For example, EPA explained that FMC had "failed to provide the data and details" or the "critical components that served to support key inputs" of "an alternate risk analysis purporting to show that aggregate carbofuran exposures to children would be safe." *Id.* at 73a. Without that information, EPA "was unable to accept the validity or utility of the analyses, let alone rely on the results." *Id.* at 74a.

In EPA's view, petitioners' request for a hearing on the percentage of crops treated was illustrative of the flaws in their overall approach. In denying petitioners' objections to the agency's use of a 100% treatment assumption, the agency reiterated its view that "county-level use data would be useful in generating reasonable estimates of PCT that might be appropriately used in drinking water assessments." Pet. App. 238a. EPA explained, however, that petitioners had offered no such data. *Ibid.* In their comments on the proposed revocation, petitioners had instead offered an analysis apparently derived from *sales* data (although petitioners had not timely submitted the underlying data themselves). In the *Final Rule*, EPA had explained at length why such sales data were inadequate and unreliable. *Id.* at 232a; see *Final Rule*, 74 Fed. Reg. at 23,066; see also Pet. App. 238a-240a (discussing the "two major prob-

lems in equating sales information with use information"). In their hearing request, however, petitioners had "not responded to EPA's explanation in the final rule of the reasons that the information and methodology on which they relied to estimate a four percent PCT was flawed." *Id.* at 232a. Instead, petitioners had "ignored EPA's extensive analysis of this issue in the final rule and simply refiled their comments on the proposal as if EPA's determination in the final rule did not exist." *Id.* at 233a; see *id.* at 330a.

EPA determined as well that, in making their hearing request, petitioners had relied on several forms of untimely-submitted material. During the comment period, petitioners had failed to submit the "modeling" or the underlying sales data, even though both were available to them at that time. Pet. App. 233a-234a; see *id.* at 330a. Moreover, to the extent petitioners' request for a hearing was based on a purported factual issue about PCT created by the "risk mitigation measures" included in the proposed revision of their FIFRA registration, that claim was not properly before the agency. *Id.* at 234a, 330a.

EPA applied a similar analysis to petitioners' handling of the "National Leaching Assessment." Petitioners had failed to submit that assessment itself with their comments to the proposed revocation, instead relying on only a summary that was inadequate to be evaluated. Pet. App. 209a-210a (citing *Final Rule*, 74 Fed. Reg. at 23,061-23,062). Petitioners had belatedly submitted a version of the Assessment along with their hearing request. EPA explained that "[b]ecause the National Leaching Assessment was available during the comment period but was withheld, this information is considered to be untimely and the [p]etitioners have waived the

right to rely on it." *Id.* at 210a. In addition, because petitioners had modified the Assessment to account for FMC's belated proposed registration amendments, it also did not provide a proper basis for objecting to the *Final Rule* issued before those amendments were offered. *Id.* at 210a-211a.

3. Petitioners filed a petition for review in the court of appeals, which denied it in relevant part. Pet. App. 1a-15a.

a. With respect to petitioners' challenge to the agency's use of a 100% PCT, the court of appeals noted that the agency had declined to consider arguments and information that had not been timely filed during the comment period before the *Final Rule*. Pet. App. 7a-8a. The court rejected petitioners' contention that they had a right under the FFDCA to "rais[e] in [their] objections issues that could have been but were not raised in the comments." *Id.* at 8a. The court noted that EPA has "broad discretion to 'fashion [its] own rules of procedure' in order to implement the multi-stage procedures required by the FFDCA," and that it was a proper exercise of that discretion to require "issues to be raised at the first available opportunity." *Ibid.* (quoting *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 544 (1978)). The court explained that EPA had consistently enforced that requirement and, in the *Proposed Rule*, had "specifically reminded parties interested in the present proceeding of the practice." *Ibid.* (citing 73 Fed. Reg. at 44,865). Without this requirement, the court explained, "the comment period would be redundant and superfluous," and a party would have no "incentive to raise an issue at the comment stage if it could wait without prejudice to see whether doing so was still necessary at the objection stage." *Id.* at 8a-9a.

The court of appeals further held that EPA had properly declined "to consider any of petitioners' arguments based upon" FMC's proposed registration amendments because that proposal had been submitted after issuance of the *Final Rule*, and "[o]bjections that assumed the amendments had been or would be accepted by the agency were not responsive." Pet. App. 11a. The court also concluded that EPA had properly declined petitioners' hearing request based on their "recycled" comments. *Id.* at 10a-11a. The court noted that a hearing request "must be directed 'with particularity [to] the provisions of the [final rule] deemed objectionable.'" *Id.* at 11a (brackets in original) (quoting 21 U.S.C. 346a(g)(2)(A)). By ignoring EPA's reasons for rejecting their comments previously, the court explained, petitioners had "failed to lodge a relevant objection." *Ibid.*

b. The court of appeals concluded that EPA had properly denied petitioners' request for a hearing on the question "whether carbofuran will be applied in areas with soil that is 'vulnerable' to the carbofuran leaching into the groundwater." Pet. App. 12a-13a. The court explained that, because petitioners had failed to timely submit the study on which they based their argument, the agency had properly rejected it. *Id.* at 13a. The court of appeals also observed that, even if the study had been properly before the agency—thus creating a "dispute between experts"—the court would not reverse an agency's finding that "there is no material issue of fact" based on "[m]ere differences in the weight or credence given to particular scientific studies." *Ibid.* (quoting *Community Nutrition Inst.* v. *Young*, 773 F.2d 1356, 1363 (D.C. Cir. 1985), cert. denied, 475 U.S. 1123 (1986)).

ARGUMENT

The court of appeals' affirmance of EPA's decision not to hold an evidentiary hearing turned on proceeding-specific facts and circumstances and does not conflict with any decision of this Court or another court of appeals. This case would be a poor vehicle for examination of the legal standard for invocation of the FFDCA's hearing provision because both the hearing denial and the court of appeals' affirmance of it were largely based on petitioners' serial waivers and failures to comply with standard rulemaking procedural requirements. In any event, EPA's rejection of petitioners' hearing request was fully consistent with all applicable statutory and regulatory requirements. Further review is not warranted.

1. Contrary to petitioners' contention (Pet. 16), this case does not present the question whether 21 U.S.C. 346a(g)(2) requires EPA to conduct a hearing when there is "a bona fide dispute among experts over material facts." Pet. 16. Petitioners do not identify any "expert" (Pet. 16) opinion that could have created a legitimate factual dispute in this case. In particular, petitioners' challenge to EPA's assumption of a 100% crop treatment percentage did not create such a dispute. EPA agreed with FMC that reliable "county-level use data would be useful in generating reasonable estimates of [the percentage of crops treated] that could be used in drinking water assessments." *Final Rule*, 74 Fed. Reg. at 23,066. Petitioners did not submit any such data, however. They instead submitted an analysis based on *sales* data, but failed to timely submit those data or adequately explain the methodology they had used to derive usage estimates from them. *Ibid.* In the *Final Rule*, EPA explained in detail why it could not rely on petition-

ers' inadequately-explained analysis of the sales data. *Ibid.* Instead of responding to that refutation of their analysis, petitioners' hearing request simply resubmitted their prior contentions. Pet. App. 232a-233a.

In declining to hold a hearing to determine the percentage of crops treated with carbofuran, EPA thus did not find petitioners' proffered "expert" opinion on a factual question less persuasive than some other "expert" opinion. Instead, EPA found that petitioners had failed to submit any expert opinion directly addressing the relevant question. Accordingly, in the absence of any reliable data supporting a lower figure, the agency adhered to its assumption of 100% crops treated "due to the large uncertainties in the actual PCT on a watershed-by-watershed basis." Pet. App. 235a. EPA agreed that "[i]n most cases, * * * it is unlikely that 100% of the crop will be treated with a single pesticide in most watersheds, particularly in larger watersheds." *Id.* at 235a-236a. It nevertheless found that, "for small watersheds, it is reasonable to assume that an extremely high percentage of the crops in the watershed may be treated." *Id.* at 236a. Petitioners' inadequate submissions failed to create any "bona fide" dispute concerning that assumption.

The court of appeals' analysis of this question was likewise based on petitioners' procedural lapses. In affirming EPA's decision to deny a hearing on the percentage of crops treated with carbofuran, the court upheld the agency's conclusions that petitioners' empirical submissions were "untimely and forfeited" (Pet. App. 8a), and that their "recycled" comments failed entirely

to "address[] the responses EPA had made to them in" the *Final Rule* (*id.* at 10a-11a).[1]

There was also no "bona fide dispute" between experts regarding "whether carbofuran will be applied in areas with soil that is 'vulnerable' to the carbofuran leaching into the groundwater." Pet. App. 12a. Petitioners' claims in that regard were based on the conclusions they attributed to a "National Leaching Assessment." *Final Rule*, 74 Fed. Reg. at 23,061. EPA concluded, however, that it was not able to "confirm or negate" petitioners' contentions based on the Assessment because petitioners had failed to submit the Assessment to the agency for review. *Ibid.* Petitioners belatedly submitted the Assessment (modified to account for FMC's intervening proposal to amend carbofuran's registration) with their request for a hearing. Pet. App. 210a. Because the Assessment "was available during the comment period but was withheld," however, EPA concluded that petitioners' submission was "untimely." *Ibid.* The court of appeals affirmed EPA's waiver finding on groundwater, concluding that the agency had "properly refused to consider" the National Leaching Assessment because it "could have been but was not submitted with the petitioners' [c]omments" on the *Proposed Rule*. *Id.* at 13a.[2]

[1] Only after concluding that the hearing denial was supported by petitioners' procedural failures did the court of appeals briefly note that, "[i]n any event," EPA had not "abused its discretion in concluding the petitioners failed to present sufficient evidence to warrant using a PCT lower than 100 when estimating concentrations of carbofuran in surface water." Pet. App. 11a.

[2] The court of appeals' subsequent statement that it would not "overturn" EPA's determination that no material issue of fact existed despite petitioners' claim of a "dispute between experts" was thus unnecessary

In sum, both EPA's denial of a hearing in this case, and the court of appeals' affirmance of that decision, rested independently on the agency's findings that petitioners had failed to properly present the data and arguments they attempted to advance in support of their hearing request. Cf. Pet. C.A. Br. 19 (acknowledging that in denying the hearing request, EPA had placed "overwhelming reliance" on waiver findings).

2. Petitioners contend that EPA improperly relied on a "novel rule * * * categorically to reject objections as either 'too early' or 'too late.'" Pet. 14; see Pet. 26-31. Contrary to petitioners' contentions, EPA properly applied longstanding waiver and exhaustion principles to the circumstances of this case, and nothing in the agency's analysis warrants this Court's review.

a. At the outset of the proceeding, EPA warned petitioners and other potential commenters that if they "anticipate[d] that [they] may wish to file objections to the final rule, [they] must raise those issues in [their] comments on this proposal." *Proposed Rule*, 73 Fed. Reg. at 44,865. The agency also stressed that "[i]ssues not raised during the comment period may not be raised as objections to the final rule, or in any other challenge to the final rule," and that "EPA will treat as waived, any issue not originally raised in comments on this proposal." *Id.* at 44,864-44,865.

In disregard of those warnings and the ordinary exhaustion principles they reflect, petitioners failed to submit the studies and data on which they attempted to rely in their comments on the proposed revocation. When

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and was, at most, an alternative to its principal holding that EPA had "properly refused to consider" the National Leaching Assessment because it was untimely filed. Pet. App. 13a.

EPA explained in the *Final Rule* that petitioners' decision to withhold relevant information had prevented the agency from evaluating their claims, petitioners belatedly submitted the missing information along with their hearing request. By that time, however, it was too late. Just as EPA had stated it would do, it treated claims based on untimely submitted information as waived.

Likewise, petitioners' hearing request repeatedly relied on "recycled" comments that petitioners had submitted before EPA issued the *Final Rule*. Pet. App. 10a. In the *Final Rule*, EPA explained at length why it had rejected the contentions made in petitioners' comments. Rather than responding to that analysis, petitioners mechanically resubmitted the same comments as if EPA's findings did not exist. The problem was not that petitioners had submitted the comments "too early." Cf. Pet. 14. Rather, those resubmitted comments were unsuited to the task at hand because they were wholly unresponsive to the specific agency decision (the *Final Rule*) to which they were nominally offered as objections.

Petitioners' resubmitted comments might roughly be analogized to a petition for rehearing en banc that simply incorporates portions of a party's earlier brief to the panel, without discussing the panel's analysis or attempting to explain why it is wrong. It is neither unfair nor logically inconsistent to require that a rehearing petition must specifically identify the alleged flaws in the panel opinion (and in that respect must be meaningfully different from the party's brief to the panel), while precluding the assertion of wholly new arguments (except to the extent that the panel decision raises new issues that the party had no prior opportunity to address, cf. note 3, *infra*). The same is true here.

b. Petitioners contend that they had an unqualified right under the FFDCA and EPA's regulations to object to a final revocation on any basis at all, whether or not they had properly preserved the contention at the comment stage of the proceeding. Pet. 27-29. Petitioners identify no court of appeals that has adopted that reading of the statute and implementing regulations, and EPA properly rejected it.

As EPA explained, the hearing provision in 21 U.S.C. 346a(g) is "part of a coherent statutory structure inextricably linked to the FFDCA's informal rulemaking procedures and section 553 of the [Administrative Procedure Act (APA)]." Pet. App. 88a. As petitioners conceded before the agency, Section 346a "establishes an informal rulemaking process" governed by 5 U.S.C. 553, and it is settled that "the failure to raise factual or legal issues during the comment period of a rulemaking constitutes waiver of the issues in further proceedings." Pet. App. 88a. Although the FFDCA "in certain limited circumstances supplements the informal rulemaking with a hearing," it "does not fundamentally alter the requirements applicable to informal rulemakings." *Id.* at 90a. The rulemaking phase of the proceeding is designed "to resolve the issues that can be resolved, and to identify and narrow any remaining issues for adjudication." *Ibid.*

The subsequent phase where a party may request a hearing "does not represent an unlimited opportunity to supplement the record, particularly with information that was available during the comment period, but that commenters have chosen to withhold." Pet. App. 90a. EPA explained that acceptance of petitioners' contrary view—under which a party could submit any evidence and contentions as part of a request for a hearing, un-

hindered by any waiver rules—would "render the rulemaking portion of the process entirely duplicative of the hearing, and thus, ultimately meaningless." *Id.* at 91a. Accordingly, EPA explained, the agency had for years consistently enforced the rule that parties could not withhold evidence or contentions during the comment phase and then raise them for the first time when requesting a hearing. *Id.* at 93a-94a.

While acknowledging that the FFDCA "provides little guidance on the objections that a party may raise," the agency concluded that "the relative silence of the statutory provision does not mean that EPA is required to allow parties to raise any and all objections; rather it means that Congress left the question of what constitutes 'reasonable grounds' for EPA to resolve." Pet. App. 92a. It was "undeniably a reasonable exercise of discretion to ensure that the rulemaking is not an opportunity for one party to waste the time and resources of all parties—both the government and other rulemaking participants—by failing to raise all of their issues or withholding information for the purpose of surprising the government at a later point during the proceeding." *Id.* at 93a.

"Absent constitutional constraints or extremely compelling circumstances the administrative agencies should be free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties." *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 543 (1978) (internal quotation marks and citation omitted). No such "extremely compelling circumstances" (*ibid.*) are present in this case, where EPA simply applied a commonplace requirement of administrative exhaustion. See *United States* v. *L.A. Tucker Truck*

Lines, 344 U.S. 33, 37 (1952) ("[A]s a general rule * * * courts should not topple over administrative decisions unless the administrative body not only has erred, but has erred against objection made at the time appropriate under its practice."). Moreover, EPA's interpretations of both the FFDCA and the agency's own implementing regulations are entitled to deference, see *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 843 (1984); *Chase Bank USA, N.A.* v. *McCoy*, 131 S. Ct. 871, 880 (2011), and petitioners fail to demonstrate that their contrary reading is compelled by the statutory or regulatory text.[3]

c. The court of appeals' affirmance of EPA's application of its waiver rule in this case does not conflict with any decision of this Court or another court of appeals. Petitioners' reliance (Pet. 30) on *Sims* v. *Apfel*, 530 U.S. 103 (2000), is misplaced. That case involved procedures specific to the Social Security Act that were "inquisitorial rather than adversarial" and in which the reviewing administrative body did "not depend much, if at all, on claimants to identify issues for review." *Id.* at 111-112 (opinion of Thomas, J.). In FFDCA tolerance rulemakings, by contrast, normal administrative-exhaustion re-

[3] EPA did not, as petitioners contend (Pet. 28), rely on its waiver rules to bar petitioners from raising issues or evidence at the hearing stage that responded to changes in EPA's reasoning between the *Proposed* and *Final Rules*. As explained above, EPA's analysis of the PCT issue did not change between the *Proposed Rule* and the *Final Rule*. On groundwater, EPA used the same modeling in the *Final Rule* that it had in the *Proposed Rule*; the only modification in the analysis was the one required by FMC's proposal to restrict use of carbofuran to limited geographic areas. A change in the scope of analysis required by a party's own decision to withdraw use of its product from many parts of the country does not constitute "a new rationale." *Ibid.*

quirements are appropriate because the interested parties are responsible for identifying and developing the issues that the agency is to resolve. For that reason, the courts of appeals have generally held that *Sims* is not applicable to administrative rulemaking proceedings. See *Advocates for Hwy. & Auto Safety* v. *Federal Motor Carrier Safety Admin.*, 429 F.3d 1136, 1149 (D.C. Cir. 2005); *Universal Health Servs., Inc.* v. *Thompson*, 363 F.3d 1013, 1020 (9th Cir. 2004) (*Sims* "turned on the unique nature of the Social Security benefit proceedings and offers no guidance relevant to rulemaking.").

The Third and Ninth Circuit decisions on which petitioners rely (Pet. 30-31) do not conflict with the decision in this case because none of them addressed a two-step administrative process analogous to proceedings under the FFDCA. The court below found EPA's waiver procedure reasonable specifically because it ensured that both steps of the tolerance-revocation process were meaningful. Pet. App. 8a-9a. Moreover, petitioners were explicitly warned about the waiver rule from the outset of the proceeding. Under those circumstances, there is no support for petitioners' contention that other courts of appeals would have disapproved EPA's application of its longstanding waiver rules.

3. Even if EPA's denial of petitioners' hearing request were not independently justified by petitioners' serial waivers, this case would present no question warranting further review.

a. The FFDCA requires EPA to "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." 21 U.S.C. 346a(g)(2)(B); see 40 C.F.R. 178.32(b)(2) ("An evidentiary hearing will

not be granted * * * if the Administrator concludes that the data and information submitted, even if accurate, would be insufficient to justify the factual determination urged."). A statutory provision like this one, triggered by a finding that something is "'necessary' * * * is an inherently discretionary standard that clearly invites further definition by the [agency]." *AFL-CIO* v. *Chao*, 409 F.3d 377, 393 (D.C. Cir. 2005) (Roberts, J., concurring in part and dissenting in part) ("Determining what is 'necessary' unavoidably calls for the exercise of the [agency's] judgment and expertise.").

Under the FFDCA's plain language, moreover, a hearing is required only "if and to the extent *the Administrator determines* that such a public hearing is necessary." 21 U.S.C. 346a(g)(2)(B) (emphasis added). Reviewing courts have distinguished between statutory requirements that depend on "the objective existence of certain conditions," and those that are based on an agency's "determination that such conditions are present." *AFL-CIO*, 409 F.3d at 393 (Roberts, J., concurring in part and dissenting in part) (quoting *Kreis* v. *Secretary of the Air Force*, 866 F.2d 1508, 1513 (D.C. Cir. 1989)). A "statute phrased in the latter terms fairly exudes deference" to the agency. *Ibid.* (internal quotation marks and citation omitted); see *Webster* v. *Doe*, 486 U.S. 592, 600 (1988).

Particularly in light of the broad statutory delegation of authority to EPA, the court of appeals properly applied a "necessarily deferential" standard to EPA's decision not to hold a hearing in this case. Pet. App. 7a (internal citation omitted); 5 U.S.C. 706. Other court of appeals decisions, including some cited by petitioners, apply the same standard. See, *e.g.*, *Puerto Rico Aqueduct & Sewer Auth.* v. *EPA*, 35 F.3d 600, 604 (1st Cir.

1994) (affirming EPA hearing denial under "the busy intersection of three deferential standards of review": the APA's arbitrary or capricious standard; "the extra measure of deference with regard to factual questions involving scientific matters in [an agency's] area of expertise"; and "the respect usually accorded an agency's interpretation of a statute it is charged to execute" as well as its own regulations), cert. denied, 513 U.S. 1148 (1995); *Hynson, Westcott & Dunning, Inc.* v. *Richardson*, 461 F.2d 215, 219-220 (4th Cir. 1972) (in making hearing determinations, an agency's discretion cannot be exercised arbitrarily), aff'd as modified, 412 U.S. 609 (1973).[4]

b. In arguing that the decision below conflicts with rulings of this Court and other circuits (Pet. 20-26), petitioners rely on decisions that address evidentiary-hear-

[4] Petitioners are wrong in arguing (Pet. 10-11, 17) that instances where EPA evaluated petitioners' evidence demonstrate that EPA failed to apply the appropriate standard to determine whether a hearing was warranted. For example, in accusing EPA of impermissibly "weighing" the evidence, petitioners quote out of context an EPA statement referencing "the totality of the evidence." Pet. 11 n.3 (quoting Pet. App. 127a). When the entire sentence from which the quote is taken is considered, however, it is apparent that EPA was properly applying the hearing standard. In full, EPA stated that it was denying the hearing request because "[t]he totality of the evidence submitted fails to demonstrate a reasonable possibility that exclusive reliance on carbofuran brain data will be protective, largely because [petitioners] have failed to proffer any evidence on several points that are critical to their argument." Pet. App. 127a-128a. EPA may properly deny a hearing on an argument that has no reasonable possibility of success due to a failure to proffer sufficient evidence, and such a denial does not amount to an improper weighing of evidence at the hearing-request phase. See 40 C.F.R. 178.32(b)(2).

ing requirements under dissimilar statutory and regulatory provisions.

Petitioners' reliance (Pet. 20-22) on this Court's decision in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) (*Hynson*), is misplaced. The Court in *Hynson* upheld the authority of the Food and Drug Administration (FDA) to follow a summary judgment-type procedure when determining whether a party has met its burden of establishing entitlement to an evidentiary hearing. *Id.* at 615-622. The Court concluded, however, that the FDA had erroneously denied a hearing in the case before it. *Id.* at 623.

For two principal reasons, *Hynson* does not support petitioners' theory in this case. First, the Court in *Hynson* did not explain its rationale in finding that the FDA's denial of a hearing was erroneous. The Court's entire discussion of that question came in a two-sentence statement of its bare holding. See 412 U.S. at 623 ("There is a contrariety of opinion within the Court concerning the adequacy of Hynson's submission. Since a majority are of the view that the submission was sufficient to warrant a hearing, we affirm the Court of Appeals on that phase of the case.").

Second, *Hynson* involved statutory and regulatory provisions different from those at issue here. *Hynson* involved a statutory provision that broadly provided an "opportunity for hearing," 412 U.S. at 620 (quoting 21 U.S.C. 355(e)), and a particular FDA regulation construing it, *ibid.* (citing 21 C.F.R. 130.14(b) (1972)). Accordingly, the issue in *Hynson* was whether a party requesting an FDA hearing had met *that* "statutory standard[] as particularized by [*that*] regulation[]." *Ibid.* And unlike 21 U.S.C. 346a(g)(2)(B), neither the statute nor the regulation at issue in *Hynson* gave agency offi-

cials broad discretion to "determine[]" whether a hearing was "necessary." Cf. p. 23, *supra*.

There is likewise no conflict between the decision below and the court of appeals decisions on which petitioners rely. The Fourth Circuit in *Hynson* held that the FDA had acted arbitrarily in denying a hearing request by a pharmaceutical company that had submitted scientific evidence showing that its drug was effective. 461 F.2d at 221-222. As noted above, however, *Hynson* involved a different regulatory scheme, and, in any event, nothing in the Fourth Circuit's fact-specific review of the record in that case conflicts with the decision below.

Petitioners' reliance on *Pactra Industries, Inc.* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977), is also misplaced. That case involved a different section of the FFDCA, 21 U.S.C. 371(e), and, contrary to petitioners' characterization, (Pet. 24), the Ninth Circuit determined that Section 371(e) did *not* incorporate the summary judgment-type standard at issue here. Under the provision at issue in *Pactra*, "[h]earings are mandatory upon request," Pet. App. 106a, while here, they are to be held only "if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." 21 U.S.C. 346a(g)(2)(B).

4. Contrary to petitioners' contention (Pet. 31), this is not a case of "exceptional national importance." Petitioners state that "[f]or more than four decades, EPA has thwarted Congress's express hearing requirement under the FFDCA" by failing to hold hearings. *Ibid.*;

see *id.* at i, 3, 16 (repeating claim).[5] During the "four decades" prior to petitioners' request, however, EPA ruled on only *two* other such hearing requests. See 73 Fed. Reg. 42,683 (2008); 59 Fed. Reg. 33,684 (1994).[6] EPA's isolated denials of those evidentiary-hearing requests, under a statute that requires such hearings only "if and to the extent the Administrator determines" they are "necessary," 21 U.S.C. 346a(g)(2)(B), raise no issue of broad importance.

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[5] In support of their hyperbolic claim that EPA has worked a "nullification of an Act of Congress," petitioners state that EPA "dismissively refers to hearings as 'time-consuming' and 'unnecessary.'" Pet. 19 (quoting Gov't C.A. Br. 5, 56); see Pet. 15 (same). The full contexts in which the quoted language appears make clear, however, that the government's argument below was consistent with routine waiver and exhaustion principles. See Gov't C.A. Br. 5 ("EPA reasonably interprets the statute's two-stage administrative process in a way that ensures *both* stages of the process will be meaningful. Its interpretation reflects Congress' intent to limit the use of a time-consuming evidentiary hearing to those instances in which a genuine material factual issue exists as to EPA's factual determinations in a final revocation rule."); *id.* at 56 ("Without a waiver doctrine that limits the second stage to a review of the matters determined in the first stage, not only would the rulemaking phase be rendered superfluous, but parties would be encouraged to engage in gamesmanship in the hope of delaying ultimate EPA resolution of the matter and EPA could be forced to devote limited resources to hearings which may have been unnecessary.").

[6] Since EPA's denial of the evidentiary-hearing request regarding carbofuran, the agency has denied one additional hearing request. See 75 Fed. Reg. 55,997 (2010). Petitioners' remaining citations to EPA decisions (Pet. 16 n.5) do not involve evidentiary-hearing requests under the FFDCA.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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