

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 22, 2010

Decided July 23, 2010

No. 09-1284

NATIONAL CORN GROWERS ASSOCIATION, ET AL.,
PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY AND LISA PEREZ
JACKSON, ADMINISTRATOR,
RESPONDENTS

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

Kenneth W. Weinstein argued the cause for petitioners. With him on the briefs were *Claudia M. O'Brien*, *Drew C. Ensign*, and *Dylan M. Fuge*.

Lawrence S. Ebner was on the brief for *amicus curiae* CropLife America in support of petitioners.

Alan D. Greenberg, Attorney, United States Department of Justice, argued the cause for respondent. With him on the brief was *Laurel Celeste*, Attorney, U.S. Environmental Protection Agency.

Jason C. Rylander was on the brief for *amici curiae* American Bird Conservancy, Inc., et al. in support of respondents.

Before: GINSBURG, TATEL and GRIFFITH, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* GINSBURG.

GINSBURG, *Circuit Judge*: The National Corn Growers Association, the National Sunflower Association, the National Potato Council, and FMC Corporation petition for review of the order of the Environmental Protection Agency denying their objections to the EPA's Final Regulation revoking all "tolerances" for the pesticide carbofuran. We grant the petition for review in part and accordingly vacate the EPA's final rule to the extent it revoked import tolerances for carbofuran. We deny the petition for review in all other respects.

I. Background

The EPA regulates pesticides pursuant to two federal statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, and the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 356a. The FIFRA establishes a registration system under which the EPA controls the sale, distribution, and use of pesticides. No one may sell a pesticide unless it has been properly registered with the EPA, pursuant to the FIFRA, for a particular use, which requires showing that, so used, the pesticide will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C).

Pursuant to the FFDCA, the EPA determines the maximum amount of a pesticide residue, which the statute terms a "tolerance," that may remain on or in raw and

processed food. The EPA may establish or leave in effect a tolerance only if it is “safe,” that is, only if

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). Absent an exemption from the Administrator of the EPA pursuant to § 346a(c), a provision not here at issue, any food containing a pesticide residue that exceeds an established tolerance is deemed “unsafe” and “adulterated” and may not be moved in interstate commerce. *Id.* §§ 331, 342(a)(2)(B).

The agency is required to modify or revoke an existing tolerance it later determines is not safe, *id.* § 346a(b)(2)(A)(i), which it does by way of a multi-step process. First, in what we refer to as the “comment stage,” it publishes a notice of the proposed revocation, provides a period for public comment and, having taken the comments into consideration, issues a “Final Regulation.” *Id.* § 346a(e). Second, in what we refer to as the “objection stage,” any person may file an “objection” to and request a public evidentiary hearing on the Final Regulation, after which the EPA issues an order stating the action taken upon each such objection and request and “setting forth any revision to the regulation ... the Administrator has found to be warranted.” *Id.* § 346a(g)(2). The FFDCFA requires that an objection “specify[] with particularity the provisions of the regulation ... deemed objectionable and stat[e] reasonable grounds therefor.” *Id.* § 346a(g)(2)(A). The Act requires the EPA to hold a hearing 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.”
Id. § 346a(g)(2)(B). Under the EPA’s implementing regulations:

A request for an evidentiary hearing will be granted if the Administrator determines the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. An evidentiary hearing will not be granted on issues of policy or law.

(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 requestor 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.

(3) Resolution of the factual issue(s) in the manner sought ... would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested.

40 C.F.R. § 178.32(b).

In 2006 the EPA concluded, in a dietary risk assessment, that human exposure to carbofuran, a pesticide used to control insect infestations in a number of crops, is “above the Agency’s level of concern.”* The EPA sought to limit

* A dietary risk assessment comprises four steps: (1) identification of the toxicological hazards posed by a pesticide; (2)

exposure to carbofuran by revoking all tolerances under the FFDCA, which action would effectively ban the use of carbofuran on both domestic and imported food for human consumption. Referencing its earlier risk assessment, the EPA stated in the notice of proposed revocation that aggregate dietary exposure to residues of carbofuran is “not safe.” Carbofuran; Proposed Tolerance Revocations, 73 Fed. Reg. 44,864, 44,865/2 (July 31, 2008) [hereinafter Proposed Revocation]. Specifically, the EPA concluded (1) estimated exposure from food alone, as well as from food and water, “significantly exceed[s] EPA’s level of concern for children”; and (2) estimated exposure for both children and adults who receive their drinking water from “vulnerable” sources exceeds the EPA’s level of concern. *Id.* at 44,865/3.

The petitioners submitted extensive Comments in response to the proposed revocation. Also during the comment period, FMC, the only manufacturer of carbofuran in the United States, voluntarily cancelled its registrations under the FIFRA for all but six crops and proposed that the EPA amend the remaining registrations to limit usage in areas particularly susceptible to drinking water contamination (the “First FMC Proposal”), which proposal the EPA accepted, Carbofuran; Product Cancellation Order, 74 Fed. Reg. 11,551 (Mar. 18, 2009).

In May 2009 the EPA issued a Final Regulation revoking all tolerances for carbofuran. Carbofuran; Final Tolerance Revocation, 74 Fed. Reg. 23,046 (May 15, 2009). It concluded that although the First FMC Proposal would reduce exposure to carbofuran, the aggregate exposure from drinking

determination of the “level of concern” for humans; (3) estimation of human exposure to the pesticide; and (4) characterization of risk to humans based upon a comparison between the estimated exposure and the level of concern.

water would still exceed the level of concern with respect to both children and adults. *Id.* at 23,047/3. FMC then proposed another amendment to its registration under the FIFRA, which would further limit carbofuran usage (the “Second FMC Proposal”), and the petitioners filed Objections and a Hearing Request. In November 2009 the EPA denied the petitioners’ Objections and Hearing Request. Carbofuran; Order Denying FMC’s Objections and Requests for Hearing, 74 Fed. Reg. 59,608 (Nov. 18, 2009) [hereinafter Hearing Denial].* The petitioners seek review of that decision pursuant to 21 U.S.C. § 346(h).

II. Analysis

The petitioners contend they raised four material issues of fact with respect to the revocation of domestic tolerances, each of which merits a hearing: What are the concentrations of carbofuran in (1) surface water and (2) ground water; (3) what is the half-life of carbofuran, which is relevant in determining the extent to which an individual recovers between exposures; and (4) what is the “safe dose” of carbofuran, “*i.e.*, the level below which exposures will not result in adverse effects.” Below we conclude the EPA did not abuse its discretion by denying the petitioners’ requests for a hearing on the first two issues, which obviates the need to address the second two issues, for they are not by themselves outcome-determinative. The petitioners also contend that, because the EPA agrees the level of exposure to carbofuran from imported foods alone is safe, the agency acted arbitrarily and capriciously by revoking import tolerances. Before reaching any of these arguments, we

* Because the merits of the Second FMC Proposal were to be evaluated under the FIFRA rather than the FFDCA, the EPA’s order was “not a determination on [those] proposed registration amendments.” Hearing Denial, 74 Fed. Reg. at 59,609/2.

consider the petitioners' contention that the EPA applied the wrong standard in determining whether an evidentiary hearing was warranted.

A. Standard for Holding an Evidentiary Hearing

The parties agree the FFDCA and the EPA's regulations establish a "summary-judgment type" standard for determining whether to hold a hearing: The EPA must hold a hearing if it determines an objection raises a material issue of fact. Contrary to the position of the petitioners, however, our review of the EPA's exercise of discretion in determining whether an issue is material differs from our review of a summary judgment rendered by a district court, which we review *de novo*, *Venetian Casino Resort, LLC v. EEOC*, 530 F.3d 925, 929 (D.C. Cir. 2008).

The proper standard of review here, as we stated in another case arising under the FFDCA, is "necessarily deferential." *Cnty. Nutrition Inst. v. Young*, 773 F.2d 1356, 1363 (1985).

Mere differences in the weight or credence given to particular scientific studies, or in the numerical estimates of the average daily intake of [a substance], are insufficient. [We] will not substitute [our] judgment on highly technical and factual matters for that of the agency charged with the supervision of the industry.

Id. Rather, our review is "limited to an evaluation of whether [the agency] has given adequate consideration to all relevant evidence in the record." *Id.* at 1362.

B. Domestic Tolerances

Having established the standard of review, we turn to the question whether the issues of fact raised by the petitioners are material.

1. Concentration of carbofuran in surface water

The petitioners first argue the EPA unrealistically assumed that in any given watershed the percentage of crops treated with carbofuran (PCT) is the legal maximum, *i.e.*, 100%. According to the petitioners, “county-level sales data” show that in no county where carbofuran has been used is the actual PCT higher than 4.25, and this fact is confirmed by data measuring actual carbofuran concentrations in samples of surface water. Finally, they argue the assumption of 100 PCT is “wholly untenable” in light of the Second FMC Proposal, which would purportedly cap the PCT at 2.

The EPA refused to consider any of the documents and arguments the petitioners submitted during the objection stage that they could have but did not submit during the comment stage, holding they were, respectively, untimely and forfeited. The petitioners argue this ruling was inconsistent with the FFDCA and the EPA’s own implementing regulations, both of which provide that objections may be filed after promulgation of the Final Regulation and do not explicitly prohibit raising in the objections issues that could have been but were not raised in the comments. The EPA responds that its practice of requiring issues to be raised at the first available opportunity is a reasonable exercise of its broad discretion to “fashion [its] own rules of procedure” in order to implement the multi-stage procedures required by the FFDCA. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 534–44 (1978); *accord GTE Serv. Corp. v. FCC*, 782 F.2d 263, 274 n.12 (D.C. Cir. 1986). Not only has

the agency followed this practice in the past, *e.g.*, Mevinphos; Proposed Amendment and Revocation of Tolerances, 60 Fed. Reg. 39,302, 39,303 (Aug. 2, 1995) (“EPA believes it is appropriate to preclude review of objections raising issues not provided in comments”), but in the Proposed Revocation it specifically reminded parties interested in the present proceeding of the practice, 73 Fed. Reg. at 44,865/2 (“EPA will treat as [forfeited] any issue not originally raised in comments on this proposal”).

We agree with the EPA. As the agency points out, the comment period would be redundant and superfluous if the same concerns could be raised at the objection stage. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (statute must be interpreted as a “coherent regulatory scheme” with “all parts [fit] into a harmonious whole”); *APWU, AFL-CIO v. Potter*, 343 F.3d 619, 626 (2d Cir. 2003) (statute should be construed “so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant, and so that one section will not destroy another”). Nor would a potentially affected party have an 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. *Cf. Pinos-Gonzalez v. Mukasey*, 519 F.3d 436, 440 (8th Cir. 2008) (approving of the Board of Immigration Appeals’ rule that an issue not raised at the initial hearing before an immigration judge is forfeited for purposes of the administrative appeal). Properly viewed, the objection stage is an opportunity for internal agency review, an opportunity for an interested party to challenge — and for the agency to correct — a matter of fact, law, or policy that appeared for the first time in the Final Regulation, so-called. *Cf. ASARCO, Inc. v. FERC*, 777 F.2d 764, 772 (D.C. Cir. 1985) (section 19 of Natural Gas Act, which makes application for agency rehearing a condition of judicial

review, “is in part to insure that the [agency] has an opportunity to deal with any difficulties presented by its action *before* the reviewing court intervenes”) (internal quotation marks deleted). The EPA’s refusal to consider at the objections stage evidence and arguments that could have been but were not submitted during the comment period is also of a piece with the general rule of forfeiture we apply when reviewing agency decisions, *viz.*, that the court will not consider an argument the agency was not given a fair opportunity to consider during the rulemaking. *Nuclear Energy Inst. v. EPA*, 373 F.3d 1251, 1290 (D.C. Cir. 2004); *see also Nat’l Lime Ass’n v. EPA*, 233 F.3d 625, 640–41 (D.C. Cir. 2000) (agency need not consider information submitted after the close of the comment period); *USAir, Inc. v. DOT*, 969 F.2d 1256, 1260 (D.C. Cir. 1992) (parties “must not be encouraged to ‘sandbag’ agencies by withholding legal arguments for tactical reasons until they reach the courts of appeal”).

The EPA rejected other of the petitioners’ arguments at the objection stage on the ground they were “recycled” from the comment stage and had already been addressed when the agency promulgated the Final Regulation. Hearing Denial, 74 Fed. Reg. at 59,658/1. At that time it had rejected the petitioners’ arguments concerning the PCT because the petitioners had failed to submit much of the data and the methodology they used to arrive at their estimated PCT of 4.25. Final Regulation, 74 Fed. Reg. at 23,065/1. The agency had also noted in promulgating the Final Regulation that estimates derived from sales data fail to account for the possibility that “use patterns of carbofuran could be concentrated in certain locations, such that a large percentage of a small watershed is treated.” *Id.* at 23,066/3. In the order denying the petitioners’ Objections and Hearing Request, the EPA concluded that, although “it is unlikely that 100% of the

crop will be treated ... in most watersheds,” the possibility of 100% treatment, especially in smaller watersheds, meant the agency was “obligat[ed] to evaluate all legally permitted use practices ... and [to] ensure that all such use meets the requisite statutory standards.” Hearing Denial, 74 Fed. Reg. at 59,658/3.

We agree with the EPA that the petitioners, by simply re-submitting their Comments, without addressing the responses the EPA had made to them in the Final Regulation, “failed to lodge a relevant objection.” *Id.* at 59,658/1. By statute, an Objection and Hearing Request must be directed “with particularity [to] the provisions of the [final rule] deemed objectionable.” 21 U.S.C. § 346a(g)(2); *see also* 40 C.F.R. § 178.25(a)(2). In any event, we “will not substitute [our] judgment on highly technical and factual matters for that of the agency,” *Cnty. Nutrition*, 773 F.2d at 1363, and on this record we cannot say the EPA 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.

Finally, the EPA refused to consider any of the petitioners’ arguments based upon the Second FMC Proposal. Hearing Denial, 74 Fed. Reg. at 59,658/2. As mentioned in the preceding paragraph, an Objection and Hearing Request must be responsive to the Final Regulation; it must identify some specific error in the regulation. The Second FMC Proposal was submitted to the EPA 44 days after publication of the Final Regulation; Objections that assumed the amendments had been or would be accepted by the agency were not responsive to the Final Regulation, and the EPA properly refused to consider them.

2. Concentration of carbofuran in groundwater

The second issue of fact the petitioners claim is material to the Final Regulation concerns the concentration of carbofuran in groundwater. The petitioners' challenges to the EPA's conclusion that concentrations exceed safe levels turns, the parties agree, upon a single issue of fact, *viz.*, whether carbofuran will be applied in areas with soil that is "vulnerable" to the carbofuran leaching into the groundwater. In their Comments on the proposed revocation the petitioners had relied upon a "National Leaching Assessment" they said was done by a "panel of independent water experts" to demonstrate the geographic restrictions in the First FMC Proposal would ensure against carbofuran being used in areas with vulnerable soils. According to the petitioners, vulnerable areas include only those with

permeable soils (e.g., areas with soils greater than 90% sand and less than 1% organic matter), acidic soil and water conditions, and [where] shallow water tables predominate (e.g., where groundwater is less than thirty feet).

In the Final Regulation the EPA had noted the petitioners did not submit the National Leaching Assessment itself and said they had failed to explain sufficiently the data and methodologies underlying it. The EPA went on to find the petitioners' criteria for vulnerability were underinclusive, and gave examples of potentially vulnerable areas where carbofuran could still be used if those criteria were adopted. Final Regulation, 74 Fed. Reg. at 23,060/1, 23,078–80. Even taking the First FMC Proposal into account, the EPA had concluded, concentrations of carbofuran in groundwater would not be reduced to "acceptable levels." *Id.* at 23,080/1.

In their Objections and Hearing Request the petitioners restated several arguments they had made in their Comments and argued the Second FMC Proposal would resolve the EPA's remaining doubts about whether carbofuran would be applied to vulnerable areas. This time they submitted the National Leaching Study for support, as modified to account for the Second FMC Proposal.

The EPA denied the Objections and Hearing Request. As discussed above, it properly refused to consider evidence that could have been but was not submitted with the petitioners' Comments, as well as arguments recycled from earlier Comments and arguments based upon the unapproved Second FMC Proposal. 74 Fed. Reg. at 59653/1, 59654/3–56/1.

On appeal the petitioners characterize the question whether their criteria for “vulnerable” areas are underinclusive as a “dispute between experts,” an accurate but a fatal description. As we said in *Community Nutrition*, we will not overturn an agency's finding there is no material issue of fact based upon “[m]ere differences in the weight or credence given to particular scientific studies.” 773 F.2d at 1363.

* * *

The petitioners have failed to show a hearing was warranted on either of the first two issues of fact they raised. Therefore, we need not consider the latter two issues; as the petitioners acknowledged at oral argument, resolution in their favor of those two issues alone would not alter the outcome of the administrative proceeding. *See* 40 C.F.R. § 178.32(b)(3) (“An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the outcome requested”).

C. Import Tolerances

The petitioners contend that even if the EPA properly revoked all domestic tolerances for carbofuran, it acted arbitrarily and capriciously, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), in revoking the import tolerances for carbofuran. The EPA acknowledges that exposure to carbofuran from imported foods alone is safe. The EPA nonetheless revoked all carbofuran tolerances for imported foods, contending the petitioners failed to make a timely request that import tolerances alone be left in effect. Hearing Denial, 74 Fed. Reg. at 59,675/2.

The agency's position is untenable, for the petitioners made such a request on two occasions. First, they included in their Comments five tables representing increasing tolerances they were successively asking the EPA to maintain. One table presented their most modest proposal for retention, showing exposure estimates for "Import Tolerances ... Only." Second, the petitioners expressly stated in a letter to the EPA that they wanted the agency to retain, at minimum, import tolerances "separately, by themselves."*

The EPA's contention the petitioners never asked that import tolerances alone be maintained seems, from what counsel said at oral argument, to be premised upon the idea that a party may not make arguments in the alternative. That is a strange idea, rejection of which requires no display of learning.

* The letter was submitted after the close of the comment period but the EPA did not suggest until oral argument that the letter was untimely. See *BNSF Ry. Co. v. STB*, 604 F.3d 602, 611 (D.C. Cir. 2010) ("a forfeiture can be forfeited by failing on appeal to argue an argument was forfeited"); *Ark Las Vegas Rest. Corp. v. NLRB*, 334 F.3d 99, 108 n.4 (D.C. Cir. 2003) (argument raised for first time at oral argument is forfeited).

In sum, the petitioners asked that if all else failed, the import tolerances for carbofuran should be maintained because the EPA itself considered them safe. The EPA's decision to revoke those tolerances was arbitrary and capricious.

III. Conclusion

We grant the petition for review in part and vacate the EPA's final rule to the extent it revoked the import tolerances for carbofuran. We deny the petition for review in all other respects.

So ordered.