United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 22, 2002 Decided June 28, 2002

No. 01-1296

American Forest and Paper Association, Inc.,
Petitioner

v.

Environmental Protection Agency,
Respondent

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

Russell S. Frye argued the cause for the petitioner. Richard Wasserstrom was on brief. Christina B. Parascandola entered an appearance.

Andrew J. Doyle, Attorney, United States Department of Justice, argued the cause for the respondent. Patrice Simms and Patricia Embrey, Attorneys, United States Environmental Protection Agency, were on brief.

Before: Ginsburg, Chief Judge, Henderson and Rogers, Circuit Judges.

Opinion for the court filed by Circuit Judge Henderson.

Karen LeCraft Henderson, Circuit Judge: The American Forest and Paper Association, Inc. (Association), a national trade association of the forest, paper and wood products industry, seeks review of a notice published by the Environmental Protection Agency (EPA) denying the Association's petition to delete the substance methanol1 from the list of "hazardous air pollutants" (HAPs) pursuant to section 112(b) of the Clean Air Act (CAA), 42 U.S.C. s 7412(b). See 66 Fed. Reg. 21,929 (May 2, 2001). Section 112(b)(3)(A) requires that EPA "either grant or deny the petition by publishing a written explanation of the reasons for the Administrator's decision." 42 U.S.C. s 7412(b)(3)(a).2 We review EPA's notice of denial under the Administrative Procedure Act to determine whether it is "arbitrary, capricious, an abuse of discretion, or not in accordance with law." 5 U.S.C. s 706(2)(A).3 For the reasons set out below, we conclude

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1 Methanol, also known as "wood alcohol," is a clear liquid that is released into the air when wood is processed.

2 Section 112(b)(2) describes HAPs as

> pollutants which present, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects (including, but not limited to, substances which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise, but not including releases subject to regulation under subsection (r) of this section as a result of emissions to the air.

42 U.S.C. s 7412(b)(2).

3 The Association erroneously argues that EPA is required to issue a far more extensive decision under CAA section 307(d)(9), 42 U.S.C. s 7606(d), one "that includes the factual data on which the rule is based, the methodology used in obtaining and analyzing the data, the major legal interpretations and policy considerations underlying the rule, and a response to comments or criticisms of

EPA's explanation of its reasons for denying the delisting petition satisfies the statutory standard and we therefore deny the Association's petition for review.

I.

Section 112 requires EPA to set emission standards for "hazardous air pollutants." See 42 U.S.C. s 7412. In 1990 the Congress amended section 112 to establish a statutory list of HAPs, including methanol. See 42 U.S.C. s 7412(b)(1). Section 112(b)(2) requires that EPA "periodically review the list" and "publish the results thereof and, where appropriate, revise such list by rule, adding pollutants." 42 U.S.C. s 7412(b)(2). Section 7412(b)(3) provides that "any person may petition the Administrator to modify the list of hazardous

air pollutants under this subsection by adding or deleting a substance." Id. s 7412(b)(3)(A). EPA is required (1) to "add a substance to the list upon a showing by the petitioner or on the Administrator's own determination that the substance is an air pollutant and that emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects," id. s 7412(b)(3)(B); and (2) to "delete a substance from the list upon a showing by the petitioner or on the Administrator's own determination that there is adequate data on the health and environmental effects of the substance to determine that

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EPA's proposed action." Pet'r Br. at 45. CAA section 307(d)(9), however, by its terms applies only to "rulemakings" pursuant to the CAA sections enumerated in section 307(d)(1), 42 U.S.C. s 7607(d)(1). Section 112(b) does not contemplate a formal rule-making and is not among the sections enumerated in section 307(d)(1) (although other subsections of section 112 are included there). EPA was therefore not required to respond point-by-point to each objection raised in the Association's comments below. Its decision may be upheld as long as EPA did not "entirely fail[ ] to consider" "an important aspect of the problem." See Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

emissions, ambient concentrations, bioaccumulation or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects," id. s 7412(b)(3)(C).

The Association petitioned EPA to delist methanol in March 1996, relying on information it claimed shows exposure to methanol does not result in adverse effects to human health.4 "[T]o assess the potential for adverse human health effects due to inhalation exposure" to a particular substance EPA generally uses an "inhalation reference concentration" (RfC), 66 Fed. Reg. at 21,931, which "represents the estimated maximum exposure to a pollutant, as extrapolated from animal studies, that a human can tolerate continuously for 70 years without experiencing any adverse health effect," Chem. Mfrs. Ass'n v. EPA, 28 F.3d 1259, 1265 (D.C. Cir. 1994). Because EPA had not yet established an inhalation RfC for methanol, the Association proposed a "safe exposure level" (SEL) for the substance, asserting that "exposures at or below the SEL can be expected to produce no adverse human health effects from lifetime inhalation exposures." 66 Fed. Reg. at 21,931. The Association derived its SEL from the "Rogers Study," which examined the effect on mice of methanol exposure for seven hours per day. The Association converted the No-Observable-Adverse-Effect-Level (NOAEL) derived from the Rogers Study to a human equivalent and adjusted it for interspecies extrapolation and for individual variation. The Association offered the resulting level of 83 milligrams per cubic meter (mg/m3) as the SEL for methanol. The Association further asserted that the highest predicted 24-hour average concentration of methanol from known sources is 3.65 mg/m3. Because this maximum exposure level was below its proposed SEL, the Association claimed that methanol exposure does not cause adverse ef-

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4 The Association also offered evidence to show methanol does not cause adverse environmental effects but, because it denied the petition based on potential adverse health effects, EPA found it unnecessary "to make final determinations regarding these elements of the petition." 66 Fed. Reg. at 21,939. Accordingly, we too decline to address the environmental issues.

fects and therefore should be delisted pursuant to section 112(b)(3)(C). The Association supplemented its petition periodically until EPA published a "notice of receipt of a complete petition" on July 19, 1999. See 64 Fed. Reg. 38,668. Subsequently the Association submitted additional materials addressing the "Burbacher Study," published in October 1999, which examined the effects of methanol inhalation on primates and which the Association contended supports delisting methanol.

Following a comment period, EPA issued its notice of denial on May 2, 2001. While generally approving the studies and the methodology the Association had used, EPA disagreed with the Association's analysis in three crucial respects.

First, EPA took issue with the Association's SEL, contending it should have incorporated a "duration adjustment," to account for the difference between the Rogers Study's 7-hour daily exposure and potential human daily exposure of 24 hours;5 and, in addition, it should have been derived using the "benchmark dose" (BMD) methodology6 rather than using the NOAEL methodology as the Association did. EPA determined that recalculating the SEL using a duration adjustment and the BMD methodology "would yield an SEL on the order of 4-6 mg/m3." 66 Fed. Reg. at 21,932. Because these values "are at the approximate midpoint of the values (0.3-30 mg/m3) that might be derived from the data of the Burbacher Primate Study," EPA concluded that "a range of 0.3 to 30 mg/m3 represents the most appropriate criterion for determining whether methanol emissions may reasonably be anticipated to cause adverse human health effects" and that "24-

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5 The Association initially proposed an SEL of 24 mg/m3 which reflected a duration adjustment but subsequently advocated the higher 83 mg/m3 SEL without a duration adjustment. See Delisting Petition at 2, 30-32; 66 Fed. Reg. at 21,932.

6 BMD "is defined as the statistical lower confidence limit on the dose estimated to produce a predetermined level of change in response (the benchmark response--BMR) relative to controls." Proposed Test Rule for Hazardous Air Pollutants, 61 Fed. Reg. 33,178, 33,179-80 (1996).

hour exposures below 0.3 mg/m3 are not likely to result in adverse human health effects." 66 Fed. Reg. at 21,935-36. EPA cautioned that it was "unable to make a more precise determination at this time regarding the exposure levels at which adverse effects are likely to occur." 66 Fed. Reg. at 21,936.

Second, EPA challenged the Association's maximum 24-hour exposure level as too low. Based on the data initially submitted by the Association, EPA suggested that the "maximum 24-hour exposures to methanol emissions could be in the range of 2 to 7 mg/m3, but that such exposures may not reasonably be expected to exceed 7 mg/m3." 66 Fed. Reg. at 21,939.

Third, EPA determined that, contrary to the Association's contention, the Burbacher Study in fact supports retaining methanol on the list because it revealed several possible adverse health effects, namely, a decrease in gestation time, an increase in the number of required caesarian-section births, and, in prenatally exposed offspring, instances of a "severe wasting syndrome," concentration-related delay in sensorimotor development and lower performance on an infant intelligence test. 66 Fed. Reg. at 21,932-33. EPA concluded that, "based on the weight of evidence, ... there are reproductive and developmental health consequences following exposure to methanol in primates (Burbacher et al.) and that these effects should be considered relevant to potential risks in humans." 66 Fed. Reg. at 21,935.

Because EPA's maximum exposure level exceeded the floor of its SEL range and because the Burbacher Study, as EPA construed it, indicated potential adverse effects from methanol, EPA determined it "c[ould]not conclude that there are adequate data to determine that emissions of methanol may not reasonably be anticipated to cause any adverse effects to human health." 66 Fed. Reg. at 21,929.

The Association petitioned for review of the notice of denial on July 2, 2001.

II.

The Association raises a series of challenges to the EPA's notice of denial. We find none of them persuasive.

First, the Association asserts EPA misinterpreted the statutory standard for delisting a substance to permit it to rely on mere speculation about adverse effects. Section 112(b)(3)(C) requires that EPA delist an HAP "upon a showing by the petitioner or on the Administrator's own determination that there is adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects." 42 U.S.C. s 7412(b)(3)(C). EPA construed the statutory language to impose a "burden ... on a petitioner to demonstrate that the available data support an affirmative determination that emissions of a substance may not be reasonably anticipated to result in adverse effects on human health or the environment" so that "EPA will not remove a substance from the list of HAP based merely on the inability to conclude that emissions of the substance will cause adverse effects on human health or the environment." 66 Fed. Reg. at 21,930. We review EPA's construction of the statutory language under

the familiar Chevron analysis:

> If ... " 'Congress has directly spoken to the precise question at issue,' " we "must give effect to Congress's 'unambiguously expressed intent.' " Secretary of Labor v. F[ed. Mine Safety & Health Review Comm'n], 111 F.3d 913, 917 (D.C. Cir.1997) (quoting Chevron USA, Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842, 104 S.Ct. 2778, [2781], 81 L.Ed.2d 694 (1984)). "If 'the statute is silent or ambiguous with respect to the specific issue,' we ask whether the agency's position rests on a 'permissible construction of the statute.' " Id. (quoting Chevron, 467 U.S. at 843, 104 S.Ct. 2778, [2782], 81 L.Ed.2d 694).

Cyprus Emerald Resources Corp. v. Fed. Mine Safety & Health Review Comm'n, 195 F.3d 42, 45 (D.C. Cir. 1999).

National Multi Housing Council v. EPA, No. 01-1159, slip op. at 4 (D.C. Cir. June 7, 2002). EPA's interpretation easily passes muster under Chevron. The statutory language unambiguously places on a delisting petitioner the burden to make a "showing" that "there is adequate data" about a substance to determine exposure to it "may not reasonably be anticipated to cause" adverse effects. This is precisely what EPA has construed it to require. To the extent the Association asserts EPA improperly applied the burden by relying on speculation, its assertion dovetails with its arbitrary-and-capricious arguments, which we address next.

The Association challenges EPA's technical calculations on a variety of grounds. According EPA the "extreme degree of deference" it is due when "evaluating scientific data within its technical expertise," see Huls Am., Inc. v. Browner, 83 F.3d 445, 452 (D.C. Cir. 1996) (internal quotations and citations omitted), we find its calculations are not arbitrary or capricious.

The Association argues that EPA's decision fails a "reality check" in two respects. First, the Association points out that methanol levels far higher than the maximum predicted for industrial source exposure have been reported in unexposed, healthy humans and primates, particularly in the expelled breath of study subjects who had recently consumed substantial amounts of fruit. In the notice of denial, EPA set forth specific reasons why the methanol levels in study subjects' mouths after fruit consumption may not correspond to--and may in fact considerably exceed--the actual methanol levels in the subjects' blood. See 66 Fed. Reg. at 21,935 (noting there was "no discussion as to whether these individuals rinsed their mouths out after consuming the fruit" and no "correction for off-gassing of methanol from the residual mouth contents or stomach contents"); see also Joint Appendix (JA) 824-25. EPA also noted that the high levels of methanol measured represented "an extreme case" and that consumption of fruit sufficient to produce them "most likely

involves acute GI effects sufficient to discourage the attempt." 66 Fed. Reg. at 21,935. Second, the Association contends that pharmacokinetic models show that an SEL of 0.3 mg/m3 causes only a minuscule and inconsequential increase in an exposed subject's blood methanol level. EPA has reasonably rejected the Association's pharmacokinetic models as "not targeted to humans likely to be the most sensitive to methanol," notably pregnant women, developing fetuses and persons with enzyme and vitamin deficiencies. See Resp't Br. at 57; JA 824 (noting "uncertainty in the [Association's interspecies] extrapolations, notably characterization of pregnancy and fetal transfer" which can be addressed "with the use of newer physiologically-based pharmacokinetic models"); 755-56 (summary of meeting between Association and EPA indicating EPA scientist stated "EPA needs to see a data set of methanol levels in pregnant women").7 In addition, EPA noted the possible short window of exposure for adverse developmental effects to occur in developing fetuses and its consequent concern that, despite natural fluctuations in background methanol blood levels, there is a risk of negative effects from even short term peaks. See JA 476, 755.8

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7 The Association asserts EPA "apparently ignor[ed] the fact that the pharmacokinetic data in the HEI Report were in pregnant female primates, and those data show no effect of pregnancy on methanol distribution or metabolism." Reply Br. at 9 (emphasis original). The HEI Report acknowledged, however, that "although Burbacher found that formate did not accumulate in maternal blood, the present study does not resolve the issue of possible formate accumulation in fetal tissues." JA 449.

8 The Association challenges EPA's justifications here, and elsewhere, as improperly post hoc. The record excerpts we cite, however, reveal that EPA relied below, at least in part, on the same reasoning it espouses here. See National Mining Ass'n v. Mine Safety & Health Admin., 116 F.3d 520, 534 (D.C. Cir. 1997) ("In evaluating agency action, we look at the reasons given by the agency, not 'counsel's post hoc rationalizations.' Motor Vehicle Mfrs. [Assoc. v. State Farm, 463 U.S. 29, 50 (1983)]. ' "[W]e will, however, 'uphold a decision of less than ideal clarity if the agency's

Next, the Association challenges EPA's decision to calculate the SEL using the BMD methodology (specifically, the BMDL-5 lower confidence level) rather than the NOAEL. In the Association's view, the BMD introduces an "unexplained, unacknowledged level of conservativism," Pet'r Br. at 22,9 and is, in any event, an untested, experimental approach. "We may reject an agency's choice of a scientific model 'only when the model bears no rational relationship to the characteristics of the data to which it is applied.' " See National Wildlife Fed'n v. EPA, 286 F.3d 554, 562 (D.C. Cir. 2002) (quoting Appalachian Power Co. v. EPA, 135 F.3d 791, 802 (D.C. Cir. 1998) (citing Am. Iron & Steel Inst. v. EPA, 115 F.3d 979, 1005 (D.C. Cir. 1997); Chem. Mfrs. Ass'n v. EPA, 28 F.3d 1259, 1265 (D.C. Cir. 1994))). That is not the case here. EPA has long advocated the BMD as superior to the NOAEL because "[u]nlike the NOAEL, the BMD takes into account dose-response information." See The Use of the Benchmark Dose Approach to Health Risk Assessment, at 2 (Feb. 1995) (available at http://www.epa.gov); see also EPA Draft Benchmark Dose Technical Guidance Document, at 3 (Oct. 2000) (available at http://www.epa.gov) ("[T]he BMD approach is an alternative to the NOAEL/LOAEL approach that has been used for many years in dose-response assess-

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path may reasonably be discerned." ' Id. at 43, 103 S.Ct. at 2866 (quoting Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 286, 95 S.Ct. 438, 442, 42 L.Ed.2d 447 (1974))"); Southern Pac. Transp. Co. v. ICC, 69 F.3d 583, 594 (D.C. Cir. 1995) ("The ultimate question, however, is whether the court can discern the agency's path, based on the record and not on post hoc justifications.").

9 The Association similarly contends, in footnotes, that EPA should not have used a duration adjustment. EPA concluded "the current state of scientific understanding tends to support incorporating duration-adjustment in the petitioner's derivation of SEL," noting its position was "also consistent with studies showing that the critical period for induction of developmental toxicity from methanol exposure can be at least as short as 1-2 days." JA 476. The Association offered nothing below contradicting these conclusions or their bases.

ment. The development of this approach has been pursued because of recognized limitations in the NOAEL/LOAEL approach."). The BMD's advantages over NOAEL have also been acknowledged by private researchers, including those in the Rogers Study who calculated a BMD for methanol. See John M. Rogers et al., The Toxicity of Inhaled Methanol in the CD-1 Mouse, with Quantitative Dose-Response Modeling Estimation Benchmark Dose, 47 Teratology 175, 176-77 (1993). Thus, EPA's choice of the BMD methodology was not arbitrary.

As for EPA's choice of BMD confidence level, the Association asserted, citing its technical comments below, that the BMDL-5 adds an unjustified "level of conservativism" based on the fact that the BMDL-5 produces a much lower SEL than does the NOAEL. EPA, however, took a contrary view as did, apparently, the Rogers Study researchers who applied the identical BMD. The "presence of disputing expert witnesses" offers " 'a classic example of a factual dispute the resolution of which implicates substantial agency expertise' " and requires that we " 'defer to the informed discretion of the responsible federal agencies.' " Wisconsin Valley Improvement Co. v. FERC, 236 F.3d 738, 746-47 (D.C. Cir. 2001) (quoting Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 376 377 (1989) (internal quotation omitted)). We defer here to EPA's resolution of the dispute.

The Association also challenges EPA's determination that the "maximum 24-hour exposures could be in the range of 2 to 7 mg/m3." 66 Fed. Reg. at 21,929. We need not resolve this issue, however, because the lower exposure level the Association proposed--3.65 mg/m3--also exceeds EPA's threshold SEL of 0.3 mg/m3 (which we uphold) and therefore does not support delisting.

Next, the Association, relying on a report by the Health Effect Institute (HEI), which sponsored the Burbacher Study, asserts EPA arbitrarily attributed to methanol exposure the adverse effects observed in the Burbacher Study. We believe EPA's findings were reasonable. The HEI Report itself recognized a possible connection between methanol

and the decreased gestation time, suggesting that "[f]urther studies will be required to confirm the association between low-level methanol exposure and effects on pregnancy duration." JA 377. Similarly the HEI Report acknowledged that "prenatal methanol exposure was associated with the occurrence of a wasting syndrome in females after approximately 1 year of age" but concluded that "further investigations are needed to confirm these findings." JA 425. Nor did the HEI Report rule out methanol exposure as the cause of the increased need for caesarian-sections but simply determined that "conclusions concerning methanol exposure as a causative factor in uterine bleeding are not warranted at this time." JA 377 (emphasis added).10 Finally, the HEI Report recognized that "[m]ethanol exposure was also associated with a delay in early sensorimotor development for male infants" and that "[t]he results of the Fagan Test of Infant Intelligence indicated a possible effect of methanol exposure on visual recognition memory when complex stimuli (social problems) were used in testing." JA 425. In sum, the HEI Report confirms EPA's position that the study data indicate methanol may reasonably be anticipated to cause adverse health effects but are insufficient at this time to determine conclusively that it does or does not.

Finally, the Association claims EPA violated the express directive in section 112(b)(3)(A) that EPA "may not deny a petition solely on the basis of inadequate resources or time for review." 42 U.S.C. s 7412(b)(3)(A). We disagree. EPA reviewed the Association's petition thoroughly and at great length, repeatedly requesting additional submissions before it deemed the Association's petition complete. In the end, based on its analyses, EPA concluded, consistently with the

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10 The Association also cites an expert opinion that the researchers inaccurately concluded the caesarian-section deliveries were necessary. EPA, however, was entitled to rely on the opinion of the Burbacher Study researchers rather than on the opinion of the Association's expert. See Wisconsin Valley Improvement Co., 236 F.3d at 746-47. In any event, there is no dispute regarding the increase in vaginal bleeding. See JA 370.

statute, that the Association had not produced sufficient data to satisfy its statutory burden.11

For the foregoing reasons, the petition for review is

Denied.

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11 The Association also contends that, "[i]n at least six respects, [it] raised points in its petition that were of such import that they might have changed EPA's determination, and yet EPA failed to respond to those points or explain why it was denying the [Association's] petition in spite of those points." Pet'r Br. at 45. We reject these assertions because, as the foregoing discussion indicates, none of the six points cited (failure of the reality check, objection to the BMDL-5 methodology and the arguments against attributing to methanol exposure the neurobehavioral effects observed in the Burbacher Study) is "an important aspect of the problem" that EPA "entirely failed to consider." See Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).