

United States Court of Appeals  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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Argued February 16, 2024

Decided August 13, 2024

No. 23-1045

HUNTSMAN PETROCHEMICAL LLC,  
PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY,  
RESPONDENT

AIR ALLIANCE HOUSTON, ET AL.,  
INTERVENORS

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Consolidated with 23-1047, 23-1085

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On Petitions for Review of Final Actions  
of the Environmental Protection Agency

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*John D. Lazzaretti* argued the cause for petitioners. With him on the briefs were *Allen A. Kacenjar*, *Laura K. McAfee*, *David M. Friedland*, *Elliott Zenick*, and *Tokesha Collins-Wright*.

*Matthew Z. Leopold* and *Elbert Lin* were on the brief for *amici curiae* the Chamber of Commerce of the United States of America and the National Association of Manufacturers in support of petitioners.

*Eric G. Lasker* was on the brief for *amici curiae* Ethylene Oxide Sterilization Association and Sterigenics U.S., LLC in support of petitioners.

*Ken Paxton*, Attorney General, Office of the Attorney General for the State of Texas, *Aaron L. Nielson*, Solicitor General, and *Bill Davis*, Deputy Solicitor General, were on the brief for *amicus curiae* Texas Commission on Environmental Quality in support of petitioners. *Lanora C. Pettit*, Principal Deputy Solicitor General, entered an appearance.

*Sue S. Chen*, Senior Attorney, U.S. Department of Justice, argued the cause for respondent. With her on the brief were *Todd Kim*, Assistant Attorney General, and *Monica Derbes Gibson*, Trial Attorney, U.S. Environmental Protection Agency.

*Kathleen Riley* and *Adam Kron* were on the brief for Environmental and Public Health respondent-intervenors.

Before: HENDERSON and GARCIA, *Circuit Judges*, and ROGERS, *Senior Circuit Judge*.

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

GARCIA, *Circuit Judge*: This case concerns challenges by a chemical manufacturer and two trade associations to an EPA rule regulating emissions from certain facilities. Petitioners dispute EPA's assessment of the cancer risk from exposure to those facilities' ethylene oxide emissions. EPA addressed and

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rejected petitioners' arguments in detail, and petitioners fail to show that in doing so EPA acted arbitrarily, capriciously, or otherwise contrary to law. We therefore deny the petitions for review.

## I

Under Section 7412 of the Clean Air Act, EPA is required to tighten emissions standards if it determines that certain emissions pose an unacceptable risk to public health. 42 U.S.C. § 7412(f). This case concerns a 2020 rule that EPA promulgated to regulate emissions by Miscellaneous Organic Chemical Manufacturing facilities. *See* National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review (“Rule”), 85 Fed. Reg. 49084 (Aug. 12, 2020). EPA determined that emissions from these sources posed an unacceptable risk to public health under Section 7412, primarily due to emissions of the chemical ethylene oxide, and therefore tightened emissions standards for those sources. *Id.* at 49088, 49094. Ethylene oxide is a gas at room temperature and is used, as relevant to the Rule, to manufacture antifreeze, plastics, adhesives, and other common products. EPA concluded that for people living near these facilities, the maximum lifetime individual risk of cancer from exposure to ethylene oxide was four times what EPA generally considers acceptable. *Id.* at 49095–96 & tbl.3.

The 2020 rule calculated the lifetime individual cancer risk from exposure to these facilities' emissions by multiplying the estimated lifetime exposure to ethylene oxide for the relevant populations by EPA's assessment of the increased risk of cancer from such exposure. National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, 84 Fed. Reg. 69182, 69191 (proposed Dec. 17, 2019). EPA's cancer-

risk assessment for ethylene oxide is sometimes referred to as the “IRIS value,” after an EPA database of health hazards from various chemicals called the Integrated Risk Information System.

How EPA arrived at the ethylene oxide cancer-risk assessment and whether EPA should have relied on it in the Rule is at the heart of this appeal. EPA generated that cancer-risk assessment in an extensive, eighteen-year process that began in 1998, involved rounds of public comment and peer review by EPA’s Science Advisory Board (“SAB”), and concluded in 2016 when EPA issued a comprehensive report on the subject.

The 2016 report first explained that “strong evidence” supported the conclusion that inhalation of ethylene oxide increases the risk of certain kinds of cancer. *See* J.A. 2299; *see also* J.A. 2315–22. EPA then quantified that risk using statistical modeling. EPA focused on the risk faced by members of the public from low environmental exposures because of Section 7412’s focus on “public,” rather than occupational, health. *See* J.A. 2302. In general terms (with details to come later in this decision as relevant), EPA’s statistical modeling approach proceeded as follows. *See* J.A. 2383 fig.4-1; *see also* Oral Argument Tr. 18–19. First, EPA selected underlying data about cancer rates in populations exposed to ethylene oxide. *See* J.A. 2387–89. Second, EPA developed multiple statistical models from that data. *See* J.A. 2389–97. Third, EPA considered which of the statistical models best fit that data. *See* J.A. 2397–402. And finally, EPA used its chosen model to perform additional statistical analysis to arrive at the cancer risk from ethylene oxide exposure at low environmental exposure levels. *See* J.A. 2403–13.

Petitioners here raised complaints about EPA’s data selection and modeling choices during EPA’s eighteen-year

process of updating the ethylene oxide cancer-risk assessment. *See generally* J.A. 1847–2114. When EPA used the 2016 updated cancer-risk assessment in the 2020 rulemaking, petitioners raised similar complaints in comments on the notice of proposed rulemaking and in seeking reconsideration after EPA issued the final rule. *See generally* J.A. 100–387, 388–672, 673–1034, 3353–3560.

Petitioners asked EPA to consider, among many other things, a different model developed and proposed by Texas’s environmental agency (“TCEQ”) in May 2020. 85 Fed. Reg. at 49098. TCEQ’s model estimated a cancer risk about 3,000 times lower than EPA’s model. *See* J.A. 3708. When the comment period on the Rule closed in March 2020, the TCEQ assessment was in draft form and had not yet been subject to peer review. *See* 85 Fed. Reg. at 49098 & n.12. The TCEQ assessment was finalized a few months after the comment period closed. *See id.*

Once the assessment was finalized, petitioners sought reconsideration. J.A. 3353–3560. In February 2022, EPA granted reconsideration and solicited further public comment on the use of EPA’s ethylene oxide cancer-risk assessment in the 2020 Rule and the use of the TCEQ assessment as an alternative. Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, 87 Fed. Reg. 6466, 6467 (proposed Feb. 4, 2022). EPA issued a final reconsideration decision in December 2022. Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review (“Reconsideration Decision”), 87 Fed. Reg. 77985 (Dec. 21, 2022). The Reconsideration Decision affirmed EPA’s decision to use the IRIS value for ethylene oxide for the 2020 Rule and explained EPA’s

rejection of TCEQ's cancer-risk assessment for ethylene oxide as an alternative. *Id.* at 77985–95.

In a set of consolidated cases filed in this court in 2020, petitioners Huntsman Petrochemical LLC and the American Chemistry Council sought review of the Rule. These cases were held in abeyance pending EPA's reconsideration. After the EPA issued its Reconsideration Decision, Huntsman Petrochemical, the American Chemistry Council, and the Louisiana Chemical Association again petitioned this court for review. We severed the ethylene oxide cancer-risk assessment issues raised in the petitions challenging the Rule and consolidated them with the petitions for review of the Reconsideration Decision (which concerned the cancer-risk assessment issues, too). Mar. 28, 2023 Order.

## II

Under the APA, courts must “hold unlawful and set aside agency action” that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A); *see* 42 U.S.C. § 7607(d)(9)(A) (Clean Air Act provision requiring same). Most fundamentally, “[t]he APA’s arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

An agency action is arbitrary or capricious if the agency “entirely failed to consider an important aspect of the problem” or “offered an explanation for its decision that runs counter to the evidence before the agency.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency also acts arbitrarily and capriciously when it fails to “examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’” *Id.* (quoting

*Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

In the case of EPA’s evaluation of scientific data within its area of expertise, we accord an “extreme degree of deference.” *Miss. Comm’n on Env’t Quality v. EPA*, 790 F.3d 138, 150 (D.C. Cir. 2015) (per curiam) (quoting *City of Waukesha v. EPA*, 320 F.3d 228, 247 (D.C. Cir. 2003)). This is particularly true for statistical and modeling analysis. See *Appalachian Power Co. v. EPA*, 135 F.3d 791, 802 (D.C. Cir. 1998) (per curiam) (identifying statistics as “the prime example of those areas of technical wilderness into which judicial expeditions are best limited to ascertaining the lay of the land”). We, “as nonstatisticians,” *id.*, do not ask whether, “[l]ooking at the same data” we “would simply reach a different conclusion,” *Miss. Comm’n on Env’t Quality*, 790 F.3d at 162. Instead, we “will examine each step of EPA’s analysis to satisfy ourselves that the agency has not departed from a rational course,” and “only when the model bears no rational relationship to the characteristics of the data to which it is applied” will we conclude the use of the model was arbitrary and capricious. *Appalachian Power Co.*, 135 F.3d at 802.

### III

Petitioners’ challenges to the Rule and Reconsideration Decision fall into three groups: arguments that EPA’s modeling of the lymphoid cancer risk of ethylene oxide was arbitrary and capricious, arguments that EPA committed procedural errors in promulgating the Rule and issuing the Reconsideration Decision, and an argument that Section 7412(f) is an unconstitutional delegation of congressional authority.<sup>1</sup> We address each in turn and conclude none has merit.

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<sup>1</sup> We decline to address the issue raised only by TCEQ as amicus regarding whether EPA properly accounted for parity bias in

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A

We start with the foundational issue: EPA's modeling of the lymphoid cancer risk of ethylene oxide. Petitioners have not shown that EPA's modeling was arbitrary or capricious.

As briefly outlined above, EPA's statistical modeling approach included several steps. *See* J.A. 2383 fig.4-1; *see also* Oral Argument Tr. 18–19. EPA first chose which underlying data about cancer rates in populations exposed to ethylene oxide to use. *See* J.A. 2387–89. EPA selected data from a large-scale study conducted by the National Institute for Occupational Safety and Health (“NIOSH”), which found that sterilizer workers exposed to ethylene oxide faced higher risks of lymphoid and breast cancer. *See* J.A. 2299.

Second, EPA developed multiple statistical models from that data. *See* J.A. 2389–97. EPA developed what are called dose-response models.<sup>2</sup> A dose-response model describes incremental cancer risk based on the level of exposure to the carcinogen above any background exposures. *See, e.g.*, J.A.

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selecting breast cancer as a relevant health effect of ethylene oxide exposure. TCEQ Amicus Brief 20–22. This issue is wholly independent from those raised by petitioners and not implicated by any of the arguments they do raise. *See Michel v. Anderson*, 14 F.3d 623, 625 (D.C. Cir. 1994). Further, petitioners bury some of their contentions in footnotes. *See, e.g.*, Petitioners' Brief 32 n.39, 38 n.53; Reply Brief 21 n.8, 29 n.13. We do not consider these arguments because “[a] footnote is no place to make a substantive legal argument on appeal.” *CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014).

<sup>2</sup> EPA's assessment of overall cancer risk included both lymphoid cancer and breast cancer—the two cancers linked to ethylene oxide in the data. *See, e.g.*, J.A. 2383 fig.4-1. Because this appeal focuses on challenges regarding the lymphoid cancer model, our discussion does, too.



2389–90, 2402, 3616. EPA developed multiple potential models using the individual data points from the NIOSH study. *See* J.A. 2393, 2396.

Third, EPA determined which of the statistical models best fit the data. *See* J.A. 2397–402. EPA selected the model that best fit the data based on two calculations referred to as fit metrics and an assessment of visual fit. *See* J.A. 2396–97, 2400–01 tbl.4-6. The two fit metrics used by EPA calculated, respectively, how well the model matches (or “fits”) the underlying data and the likelihood that an observed outcome is due to chance. *See, e.g.*, J.A. 2396, 2160. EPA identified the models with lower fit metrics, indicating better fit of the model overall. *See* J.A. 2400 tbl.4-6. But while the fit metrics indicate overall fit of the model across all exposure levels, EPA explained that they may not indicate the model with the best local fit at a particular exposure range. *See* J.A. 2739, 4357. Because EPA was most interested in the effect of low levels of environmental exposures for purposes of its Clean Air Act analysis, EPA also used visual fit (essentially an assessment of how well a model visually appears to fit the data when plotted on a graph) to determine which of those models with good fit metrics best fit the data at low exposure levels. *See* J.A. 2396–97.

To make that visual fit assessment, EPA took the potential models it had developed from the individual NIOSH data and compared them to categorical averages of that data to see which model had the best visual fit at low exposure levels. *See* J.A. 2393. EPA explained that plotting model fit compared to the categorical averages of data “is a very useful and commonly used tool in epidemiology” because it allows for comparison of continuous models against the unstructured information in the relevant exposure ranges. J.A. 4349–50. Put simply, it allowed EPA to make sense of a large data set of 17,000 individual data points and see an average person’s response within a

categorical interval rather than all the variations in individual responses. *E.g.*, Oral Argument Tr. 20–21.

Based on both fit metrics and visual fit at low exposures, EPA determined that the model that best fit the data was a two-piece linear spline (essentially two straight line segments with different slopes connected at what is called a “knot”), with a steeper slope at lower exposure levels and a lower slope at higher exposure levels. *See* J.A. 2397–402. EPA further explained that “plateau-like” dose-response curves like its chosen spline model “have been seen for many occupational carcinogens” and noted several potential explanations in the scientific literature for that phenomenon. J.A. 2617; *see also* J.A. 1950, 2393.

Petitioners challenge four aspects of EPA’s modeling process and model selection: (1) EPA’s use of the NIOSH data, (2) its development and selection of its chosen two-piece spline model, (3) its rejection of petitioners’ preferred model, and (4) its rejection of petitioners’ favored studies. Within those categories, petitioners raise a litany of complaints about EPA’s choices, each of which we have carefully considered and address below. It is important to note at the outset, however, that petitioners have not identified any issue that they raised during the rulemaking process to which EPA failed to respond. They instead ask us to credit, for example, their interpretation of the data and figures in the extensive record over EPA’s. Petitioners’ arguments are of the type for which we accord EPA an “extreme degree of deference.” *Miss. Comm’n on Env’t Quality*, 790 F.3d at 150. Applying that standard, and having “examine[d] each step of EPA’s analysis to satisfy ourselves that the agency has not departed from a rational course,” we conclude that EPA adequately explained its modeling approach and decisions. *Appalachian Power Co.*, 135 F.3d at 802.

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EPA extensively explained why it chose the NIOSH study as the basis for its risk assessment, including that it was by far the largest available human study and for several reasons was “high-quality.” J.A. 2300; *see also, e.g.*, J.A. 2445–46. Petitioners raise one primary complaint about the NIOSH data: The NIOSH study tracked cancer incidence in sterilizer workers from 1938–1986 but did not have substantial directly-measured data about the levels of ethylene oxide exposure such workers faced before 1978, instead using projections based on more recent data. Petitioners’ Brief 36–38. Per petitioners, this made EPA’s reliance on the NIOSH study data arbitrary and capricious.

EPA adequately explained its reliance on the NIOSH data and its rejection of petitioners’ critiques. *See* J.A. 2445–46, 2536–38. Specifically, EPA credited the NIOSH study’s explanation that pre-1978 exposure levels could be reliably estimated using a regression model based on plant- and year-specific sterilizer volume data that was available. J.A. 2445–46. The SAB agreed with EPA that the NIOSH data was “the most appropriate dataset to use” and supported EPA’s use of it. *E.g.*, J.A. 3301.

Petitioners argue that EPA’s explanation was inadequate. Those arguments lack merit.

First, petitioners note that the SAB commented that certain of the pre-1978 exposure levels estimated in the NIOSH study were “unlikely” and “surprising.” Petitioners’ Brief 36. But, as EPA explained, the SAB was not rejecting the NIOSH data; instead, the SAB asked for EPA to respond to specific data that appeared inconsistent, and EPA adequately explained why the data were not, in fact, anomalous. *See* J.A. 2763–64, 3613.

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Second, petitioners argue that EPA ignored a 2019 study that, according to petitioners, called the NIOSH data's pre-1978 exposure levels into question. Petitioners' Brief 37. But EPA reasonably explained that it rejected that 2019 study because its methodology—which was based on interviews and other data—was not sufficiently documented to evaluate how the study's model was derived, and so the results were not reliable. *See* J.A. 4341. Further, EPA explained that the 2019 study's model projections were also inconsistent with other data. *Id.*

Petitioners also argue that the NIOSH study and EPA ignored other evidence suggesting that exposure levels early in the study period would have been much higher than what NIOSH estimated, such as evidence that sterilization work practices improved substantially over time. Petitioners' Brief 37. Again, however, EPA specifically acknowledged and addressed these assertions in its response to comments. *See* J.A. 4339–41. EPA explained, for example, that the NIOSH study did account for improvements in work practices in the relevant period. J.A. 4340. Petitioners have not shown that this explanation was arbitrary or capricious.

**2**

Petitioners' challenges to EPA's modeling process and its choice of the spline model also fail.

**a**

We begin with petitioners' arguments that EPA's modeling process was arbitrary and capricious. First, petitioners challenge EPA's use of categorical averages when assessing the visual fit of potential models. Second, petitioners challenge EPA's reliance on visual fit. Petitioners also raise two technical complaints related to the calculation of a fit metric and graphing the models.

Recall that EPA developed its potential models using the individual-level NIOSH data and then, in a subsequent stage of its model-selection process, relied on categorical averages of the NIOSH data to assess the potential models' visual fit to the data at low exposures. *See* J.A. 2386, 2396. Petitioners argue that using categorical averages was an oversimplification that led EPA to choose the wrong model. Petitioners' Brief 46–47. But EPA adequately explained why it compared the models of the individual data to categorical averages in the visual fit analysis, instead of somehow visually assessing how well the models fit 17,000 individual data points on a graph. J.A. 4349–51. EPA explained that plotting model fit using categorical averages of data “is a very useful and commonly used tool in epidemiology” because it allows for visual comparison of continuous models against the unstructured information in the relevant exposure ranges. J.A. 4349–50. EPA further explained that comparison was appropriate where the categorical averages were developed from the same individual-level data as the models and compared the same referent group. *Id.* Petitioners fail to show how this explanation was unreasonable or inconsistent.

Petitioners relatedly suggest that EPA's approach ran contrary to SAB feedback. Petitioners' Brief 46 n.68; Reply Brief 19. Not so. The SAB feedback recommended that the models should be developed based on the individual, not categorical data. *See* J.A. 3324. EPA complied. *See* J.A. 2393, 2396. The SAB feedback did not preclude EPA from then relying on the categorical averages in separately assessing the models' visual fit after they had been developed.

Petitioners next seek to characterize EPA's process as “simply eyeballing” the data and relying solely on visual fit to select the model it wanted. Petitioners' Brief 44–45. In fact, however, EPA selected the model that best fit the data based on both calculated fit metrics and EPA's assessment of the

models' visual fit at low exposures, not visual fit alone. *See* J.A. 2400–01, 2396–97, 2400–01 tbl.4-6. As EPA repeatedly detailed, that use of visual fit was consistent with both SAB recommendations and EPA's own guidance. *See* J.A. 4345, 4349; *see also* J.A. 3323.

Finally, petitioners raise two other technical objections related to EPA's modeling approach. First, petitioners contest one aspect of one of EPA's fit metric calculations. Petitioners' Brief 42–43. EPA used that metric to calculate how well the underlying data match (or “fit”) the model. Petitioners contend that, in those calculations, EPA should have counted the knot of its spline model (the point where the two line segments with different slopes meet) as a third estimated parameter, instead of running the fit calculations based on two parameters. But EPA addressed this contention and adequately explained why and how its calculations were based on two parameters. *See* J.A. 4356–57. Particularly given the “extreme degree of deference” we give to EPA's evaluation of scientific data within its area of expertise, petitioners have not shown that explanation was arbitrary. *Miss. Comm'n on Env't Quality*, 790 F.3d at 150. The fact that some modelers may have chosen petitioners' approach to this calculation does not automatically render EPA's approach unreasonable.

Moreover, EPA explained that using petitioners' preferred approach would not have changed its choice of model. *See* J.A. 4357–58. Petitioners have not shown otherwise, and EPA's explanation makes sense. As already explained, EPA did not simply pick the model with the best calculated fit metrics overall; rather, it picked the model with good fit metrics and the best fit at low exposures.

Second, petitioners argue that EPA misused one of its own figures in assessing the potential models. They argue, Petitioners' Brief 48, that EPA used the figure (at J.A. 2402) as

if it represented the actual cancer risk predicted by the models as opposed to the relative risk, when the model itself is clear (as EPA confirms) that it depicts relative risks. But petitioners point to nothing in the record that indicates EPA actually misused the figure in the way petitioners suggest. In fact, the record citation petitioners rely upon is to EPA's discussion of a different figure altogether; one submitted by TCEQ. *See* Petitioners' Brief 48 (citing J.A. 4352). And on reconsideration, EPA explained that it focused on the figure for the shape of the models in relation to the underlying data, just as EPA's figure says was appropriate. *See* J.A. 4354. Petitioners have provided us no basis to disturb EPA's conclusion.

**b**

We turn now to petitioners' arguments that EPA's selection of its chosen spline model was arbitrary and capricious.

First, petitioners argue that EPA's chosen model lacks biological plausibility. Biological plausibility refers to the idea that the model should be consistent with understandings of the biology of cancer and how carcinogenic processes operate. *E.g.*, J.A. 2187. EPA explained its basis for concluding that its chosen model was biologically plausible and why its choice did not conflict with EPA's own guidance. *See* J.A. 2617, 2740, 2754, 4345–46. EPA described that "plateau-like" dose-response curves like its chosen spline model "have been seen for many occupational carcinogens" and cited potential explanations in the literature for that response. J.A. 2617; *see also* J.A. 1950, 2393. Petitioners in their opening brief do not directly challenge EPA's explanation that similar dose-response models are used for other carcinogens.

Second, petitioners argue that EPA's chosen model is inaccurate compared to real-world data, as calculated in the

TCEQ “reality check.” Petitioners’ Brief 49–51, 55–57. That “reality check” is a statistical analysis that ran EPA’s model against real-world data to gauge the accuracy of the model’s predictive power. J.A. 4386–88. Here, the TCEQ reality check compared the number of lymphoid cancer deaths predicted by EPA’s model with the number of lymphoid cancer deaths that actually occurred in the NIOSH study data. *See id.* TCEQ concluded from this reality check that EPA’s model significantly overpredicted the number of lymphoid cancer deaths from ethylene oxide exposure compared to the real-world data on which the model was based. *See id.*

EPA adequately explained, however, why the TCEQ reality check erred and thus did not call the accuracy of EPA’s model into question. *See id.* EPA explained that the TCEQ reality check did not appropriately account for the “healthy worker effect” in its calculations and thus misused EPA’s model. J.A. 4386. As EPA detailed, the healthy worker effect is often seen in occupational epidemiology and reflects a selection bias that leads to lower disease rates among workers (like those involved in the NIOSH study) than the general population. *Id.* Petitioners counter that TCEQ did, in fact, account for a healthy worker effect. Reply Brief 29. But as EPA explained, the healthy worker effect that TCEQ accounted for (15 to 16%), J.A. 3752, was materially smaller than the effect indicated by the relevant data (22 to 28%), J.A. 4387; *see also* J.A. 4333–34. Petitioners did not address that explanation in their briefing. Cognizant of our limited role in assessing EPA’s evaluation of scientific data within its area of expertise, we find this explanation adequate. *Miss. Comm’n on Env’t Quality*, 790 F.3d at 150.

We turn next to EPA’s rejection of the TCEQ model petitioners asked EPA to endorse. EPA adequately explained



why it rejected that model: The TCEQ model did not fit the data, and EPA's chosen model did. *See* J.A. 4346–49. The TCEQ model was a single line with a constant shallow slope at both lower exposure and higher exposure levels. *E.g.*, J.A. 4353. EPA explained that the TCEQ model was inconsistent with the data, J.A. 4346, and with the pattern of all the other model results indicating a plateauing response with a relatively steeper slope in the lower exposure range of the NIOSH data, a pattern the SAB specifically recognized, J.A. 4349. EPA concluded that the TCEQ model's inflexible shape thus prevented it from usefully representing the NIOSH study data. *Id.*; *see also* J.A. 4356, 4358.

Petitioners in effect argue that, had EPA not made the purported errors addressed above in developing and selecting its model, EPA would have selected the TCEQ model. But, as described above, EPA reasonably developed and selected its chosen spline model and adequately explained its reasons for doing so.

As noted above, one of petitioners' complaints pertained to EPA's use of figures representing the models. But, as previewed, EPA's reading of graphs does not undermine its rejection of the TCEQ model. *See* J.A. 4350–52. Per EPA, TCEQ purported to "adjust" an EPA figure that graphed the models to show how the TCEQ model was in fact consistent with the other models and the data. *See* J.A. 3799–800, 4350–52. But, as EPA explained, that "adjusted" figure inappropriately shifts the TCEQ model vertically—and while this shift makes the TCEQ model appear more consistent with the other modeling results, it is inappropriate to simply shift the model up on the y-axis. J.A. 4350–51. As EPA noted, the result was that TCEQ's own adjusted figure suggests that its model predicts a person with no additional exposure faces twice their baseline cancer risk—a prediction of doubled risk from no additional exposure cannot be correct. *Id.* TCEQ's

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“adjusted” figure thus does not demonstrate that its model is consistent with the other models and data. Accordingly, it does not undermine EPA’s reasons for rejecting the TCEQ model.

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Finally, we turn to EPA’s rejection of petitioners’ studies of cancer incidence in tobacco smokers and data about endogenous and background levels of ethylene oxide that petitioners contend run contrary to the NIOSH data and EPA’s model. Again, EPA acknowledged that evidence and gave an adequate explanation for not altering its conclusions.

a

Petitioners point to studies showing no link between ethylene oxide and lymphoid cancer in tobacco smokers. Petitioners’ Brief 31–33. EPA provided two reasons for why the conclusions of those studies could not be relied on. *See* J.A. 4328, 4365–66. Petitioners fail to undermine either.

First, EPA explained that the studies lack a quantitative analysis of the relationship between lymphoid cancer and ethylene oxide specifically. J.A. 4365–66. The studies did not account for the interactions between the multiple carcinogens in cigarette smoke, and thus faced the issue of what EPA terms on appeal “confounding exposures.” EPA also explained that even if the studies had been limited to the relationship between ethylene oxide and lymphoid cancer, the studies still lacked a sufficient quantitative analysis of that relationship showing how the studies’ observed lymphoid-cancer rates compared with the rate of non-smokers. J.A. 4365–66.

Petitioners do not even acknowledge the “confounding exposure” explanation in their opening brief. Petitioners argue on reply that EPA did not provide that rationale in the rulemaking. Reply Brief 26–27. EPA did not use that phrase, but in substance it provided the very same rationale it repeats

on appeal. *See* J.A. 4365–66. Petitioners also do not sufficiently undermine EPA’s explanation that the smoker studies they rely upon did not have a sufficient quantitative analysis to make them reliable. *See id.*

Second, EPA explained that the studies use an unvalidated method—a hemoglobin biomarker—as a proxy to measure ethylene oxide exposure. J.A. 4328, 4366. Per EPA, the method was not validated to assess the low environmental exposures that EPA was examining (in contrast to high occupational exposures), and the biomarker is a less accurate proxy regardless because smoking causes other changes that could affect it. *Id.* Petitioners forfeited any challenge to this rationale by failing to address it until their reply brief. *See Bd. of Regents of Univ. of Washington v. EPA*, 86 F.3d 1214, 1221 (D.C. Cir. 1996).

**b**

Petitioners also point to data about endogenous and background levels of ethylene oxide that they argue show such levels were higher than what EPA assumed for purposes of its model. Petitioners’ Brief 33–35; Reply Brief 27–28. Per petitioners, higher background levels would make it harder to assess additional health impacts from low environmental exposures if additional exposures were a statistically insignificant variation from background levels.

EPA acknowledged this evidence but rejected it on two grounds. First, EPA rejected petitioners’ study as “provid[ing] little quantitative data,” “highly speculative,” and offering findings of only an “exploratory and qualitative nature.” J.A. 4363. Second, EPA acknowledged that if, as petitioners suggested, there were reliable and high measurements of endogenous and background levels, that would make it more difficult to measure risks from marginal additional exposures. *E.g.*, J.A. 2475. But EPA explained that it is not possible to

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identify background levels of ethylene oxide with confidence because of how difficult it is to reliably monitor and measure such low levels. *See* J.A. 4366–67. EPA also explained how the NIOSH study mitigated these general concerns. *See* J.A. 4361. Petitioners do not directly engage with the reasons EPA gave for rejecting the studies, *see* Petitioners’ Brief 33–35; Reply Brief 27–28, and they therefore fail to show EPA acted arbitrarily or capriciously.

\* \* \*

Petitioners’ approach to statistical modeling and the TCEQ model itself may have advantages. But EPA’s explanations of its model development and selection sufficiently articulate a rational connection between the facts and the choices EPA made, including in response to petitioners’ critiques. For purposes of our arbitrary-and-capricious review, that is enough.

## **B**

We turn now to petitioners’ procedural arguments that EPA improperly relied exclusively on its cancer-risk assessment in promulgating the Rule, failed to respond to National Academy of Sciences (“NAS”) recommendations as required by 42 U.S.C. § 7607(d)(3)(C), and avoided meaningful public comment on the bases for its decision. None of these arguments has merit.

### **1**

First, petitioners contend that EPA improperly relied exclusively on its 2016 ethylene oxide cancer-risk assessment in promulgating the Rule and that this conflicted with commitments EPA made to Congress and with EPA’s own guidance. Petitioners’ Brief 25–29. Petitioners point to EPA’s commitment to Congress in a 1999 report that EPA would “consider[] all credible and readily available assessments” in

evaluating health risks from emissions of hazardous air pollutants. J.A. 4580. EPA’s guidance similarly indicates that EPA will “use all relevant information, . . . evaluate that information based on sound scientific practices[,] . . . and reach a position based on careful consideration of all such information.” J.A. 5800.

Petitioners contend that EPA broke those promises by relying exclusively on its 2016 cancer-risk assessment in this rulemaking. But EPA considered petitioners’ studies and explained why it found them unreliable. And when the TCEQ assessment became available in finalized peer-reviewed form after the close of the public comment period, EPA granted reconsideration and considered it. Nothing in EPA’s guidance or otherwise required EPA to *agree* with petitioners’ preferred studies or assessments. Instead, EPA was required to consider that information, and it did so.

Finally, petitioners suggest that EPA’s reliance on its 2016 ethylene oxide cancer-risk assessment is improper because that assessment was not subject to APA notice-and-comment or immediate judicial review. Petitioners’ Brief 28–29; *see also Chem. Mfrs Ass’n v. EPA*, 28 F.3d 1259, 1263 (D.C. Cir. 1994) (IRIS values are not final agency actions and thus are not subject to direct APA challenge). But the IRIS value is not shielded from public comment or judicial review: It is subject to public comment and can be challenged when it is used in a rulemaking, as this very case demonstrates.

Next, petitioners argue that EPA failed to respond to NAS recommendations as required by 42 U.S.C. § 7607(d)(3)(C).

But none of the NAS recommendations to which petitioners point required a response from EPA in promulgating the Rule.

For certain rules, including the Rule at issue here, 42 U.S.C. § 7607(d)(3)(C) requires EPA to include in the notice of proposed rulemaking a statement of any “pertinent findings, recommendations, and comments” by the NAS and explain any divergence in the proposed rule. In a 2011 report, the NAS reviewed EPA’s IRIS assessment for formaldehyde. J.A. 1642–1846. And in a 2014 report, an NAS committee reviewed the IRIS process generally and ongoing EPA efforts to improve it. J.A. 1471–1641. The NAS has not specifically reviewed the IRIS value for ethylene oxide.

Petitioners argue that EPA violated Section 7607(d)(3)(C) and acted arbitrarily and capriciously in not identifying the 2011 and 2014 NAS recommendations and explaining any divergence in the proposed rule. Petitioners’ Brief 38–41. But as EPA explained in responding to comments on reconsideration, the NAS reports to which petitioners point included general recommendations for the IRIS program and did not make any specific recommendations about the IRIS ethylene oxide cancer-risk assessment. *See* J.A. 4310–11. Further, EPA reasonably proceeded with the Rule without waiting for further improvements to the IRIS program generally. As the 2014 NAS report noted, EPA was undertaking efforts and making substantial progress in improving various aspects of the IRIS process generally. *E.g.*, J.A. 1496. And the NAS recommendations themselves recognized that the recommended improvements were of an ongoing nature, *e.g.*, J.A. 1623, 1626, and that those long-term efforts should not delay individual IRIS assessments, *e.g.*, J.A. 1670–71 (“[NAS] is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach.”), 1625.

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In any event, EPA stated that, even if it had made the NAS-recommended changes to the IRIS program prior to finalizing the 2016 ethylene oxide cancer-risk assessment, it would not have changed the result. J.A. 4310. Petitioners' argument to the contrary is purely speculative.

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Petitioners' final procedural argument is that EPA denied them the opportunity for "meaningful public comment" because EPA did not provide its reasons for rejecting the TCEQ assessment until the Reconsideration Decision. Petitioners' Brief 54–57. This too fails.

As already explained, the TCEQ assessment was not available in final, peer-reviewed form until after the public comment period on the rulemaking had closed. 85 Fed. Reg. at 49098 & n.12. When the final version of the TCEQ assessment became available, petitioners were able to submit it for EPA's consideration. *See* J.A. 4098–108. EPA granted reconsideration, invited public comment on the TCEQ model, and then explained why it was rejecting that alternative approach. *Id.* The Clean Air Act specifically envisions that the Administrator will "convene a proceeding for reconsideration" in this fashion if new and "central" information becomes available after the period for public comment. 42 U.S.C. § 7607(d)(7)(B). Petitioners fail to show they were deprived of a meaningful opportunity to comment.

Petitioners alternatively argue that EPA should have considered the draft, not-peer-reviewed version of the TCEQ assessment that was available during the initial public comment period. *E.g.*, Petitioners' Brief 56. But petitioners fail to show that EPA acted unreasonably in waiting to evaluate the final, peer-reviewed version, or that this was inconsistent with EPA's past practice. None of petitioners' examples involve EPA considering a draft assessment during the public comment

period. Petitioners do identify one instance in which EPA considered a draft assessment after the comment period closed, but that is not sufficient to show that EPA must always consider non-final studies during its comment periods.

More broadly, EPA provided multiple opportunities for meaningful public comment on the issues petitioners are focused on. Those opportunities included not just two rounds of public comment during the eighteen-year process leading to the 2016 cancer-risk assessment, but also an initial round of public comment and further public comment on reconsideration in this rulemaking proceeding, not to mention that EPA also responded to comments submitted outside those comment periods. *See, e.g.*, J.A. 1394–99, 1465–70, 1933–54, 2698–737, 2815–24, 4292–394. Petitioners had ample opportunity to meaningfully comment on these issues.

### C

Finally, petitioners argue that 42 U.S.C. § 7412(f)(2) is an unconstitutional delegation of congressional authority. Petitioners' Brief 57–59. Petitioners forfeited this argument by failing to raise it in the rulemaking as required by the Clean Air Act's mandatory exhaustion rule. 42 U.S.C. § 7607(d)(7)(B). Indeed, we have specifically held that the Act's mandatory exhaustion rule applies to nondelegation challenges. *Heating, Air Conditioning & Refrigeration Distribs. Int'l v. EPA*, 71 F.4th 59, 64–65 (D.C. Cir. 2023). That holding squarely applies here. Petitioners observe that in *Heating* we suggested that the Act's exhaustion requirement might not be mandatory in all circumstances. Reply Brief 30. But the footnote they point to suggested only that the requirement might not apply to cases raising certain challenges directly in district court. *Heating*, 71 F.4th at 65 n.2. That situation is not presented here.



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**IV**

For the foregoing reasons, the petitions for review are denied.

*So ordered.*