

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 16, 2010

Decided June 24, 2011

No. 09-1297

MEDICAL WASTE INSTITUTE AND ENERGY RECOVERY
COUNCIL,
PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENT

COALITION FOR RESPONSIBLE WASTE INCINERATION, ET AL.,
INTERVENORS

On Petition for Review of a Final Action
of the Environmental Protection Agency

Michael B. Wigmore argued the cause for petitioners. With him on the briefs was *Sandra P. Franco*.

Ronald A. Shipley, William L. Wehrum, James W. Rubin, and *Richard G. Stoll* were on the briefs for intervenor Coalition for Responsible Waste Incineration and *amici curiae* Manufacturers' HMIWI Coalition and Cement Kiln Recycling Coalition in support of petitioners.

Perry M. Rosen, Attorney, U.S. Department of Justice, argued the cause for respondent. With him on the brief was *Michael W. Thrift*, Counsel, U.S. Environmental Protection Agency. *Daniel R. Dertke*, Attorney, U.S. Department of Justice, entered an appearance.

James S. Pew argued the cause for intervenors Natural Resources Defense Council and Sierra Club in support of respondent. With him on the brief were *Colin C. O'Brien* and *John D. Walke*.

Before: SENTELLE, *Chief Judge*, and GINSBURG and KAVANAUGH, *Circuit Judges*.

Opinion for the Court filed by *Chief Judge* SENTELLE.

SENTELLE, *Chief Judge*: Petitioners Medical Waste Institute and Energy Recovery Council, trade associations representing the medical waste and waste-to-energy industries, respectively, petition for review of a regulation promulgated by the Environmental Protection Agency (“EPA”) setting performance standards for new and existing hospital/medical/infectious waste incinerators (“HMIWI”). Petitioners argue that the data set EPA used to establish these standards was flawed, that the agency’s pollutant-by-pollutant approach to setting target emissions levels was impermissible, and that the agency acted arbitrarily when it removed a provision exempting HMIWI from complying with the standards during periods of startup, shutdown, and malfunction. The EPA counters that this court lacks jurisdiction to review the two latter claims, and that the use of the data set was justifiable. We agree with the EPA and deny the petition for review.

3

I.

The challenged regulation, titled “Standards of Performance for New Stationary Sources and Emissions Guidelines for Existing Sources: Hospital/Medical/Infectious Waste Incinerators,” was issued pursuant to Section 129 of the Clean Air Act (“CAA”), 42 U.S.C. § 7429. The statute directs the EPA to set required levels of emissions reduction for nine listed air pollutants, as well as for opacity where appropriate. § 7429(a)(4). The statute sets forth the factors EPA is to consider in establishing the standards.

Standards applicable to solid waste incineration units . . . shall reflect the maximum degree of reduction in emissions of air pollutants listed under section (a)(4) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing units in each category. The Administrator may distinguish among classes, types . . . and sizes of units within a category in establishing such standards. The degree of reduction in emissions that is deemed achievable for new units in a category shall not be less stringent than the emissions control that is achieved in practice by the best controlled similar unit, as determined by the Administrator. Emissions standards for existing units in a category may be less stringent than standards for new units in the same category but shall not be less stringent than the average emissions limitation achieved by the best performing 12 percent of units in the category

§ 7429(a)(2). The level of emissions control identified by the Administrator pursuant to this provision is commonly known as a “maximum achievable control technology,” or “MACT,”

standard. 74 Fed. Reg. 51,368, 51,370 (Oct. 6, 2009). The minimum levels of stringency that the EPA may require are referred to as the MACT “floors.” *Id.*; see *Sierra Club v. EPA* (“*Sierra Club-HMIWI*”), 167 F.3d 658, 660 (D.C. Cir. 1999). Once the EPA establishes these floors, it is permitted to set more stringent MACT standards – that is, go “beyond the floor” – if, taking into account the factors identified in the statute, it determines that more stringent emissions limitations are achievable. 74 Fed. Reg. at 51,370. The statute also directs EPA to review and, if appropriate, revise the standards issued pursuant to this section every five years. § 7429(a)(5).

EPA first promulgated MACT standards pursuant to the CAA in September of 1997. 62 Fed. Reg. 48,348 (Sept. 15, 1997). EPA divided the HMIWI population into three subcategories (small-, medium-, and large-capacity units) and set standards for the nine listed pollutants in each category, which resulted in 27 separate floor determinations. See 167 F.3d at 660. Because it did not have enough data to calculate MACT floors for existing units based on emissions limitations actually achieved by best performing units, it used surrogate data – specifically, emissions limitations set by state regulations and permit requirements – to make its calculations. See 167 F.3d at 660-61; 62 Fed. Reg. at 48,352; 72 Fed. Reg. 5510, 5513 (Feb. 6, 2007). But for 17 of the 27 floor determinations, the share of the HMIWI population covered by the applicable regulations was less than 12 percent. 167 F.3d at 661. In order to meet the statutory requirement that the MACT floor in each category be set at the level of the average emissions limitation achieved by the top-performing 12 percent of units, the EPA supplemented its data set yet again, this time using “uncontrolled” data – that is, data from incinerators with no pollution controls in place. *Id.*

The Sierra Club petitioned for review of the 1997 MACT standards. This court concluded that “EPA’s method looks

hopelessly irrational.” *Sierra Club-HMIWI*, 167 F.3d at 664. We did not vacate the standards altogether, however, because “[i]t is possible that EPA may be able to explain [the standards], and the Sierra Club has expressly requested that we leave the current regulations in place during any remand, rather than eliminate any federal control at all.” *Id.* We remanded the case to the EPA for further explanation.

The 1997 regulations that remained in place after the *Sierra Club-HMIWI* decision were fully implemented by September 2002. 72 Fed. Reg. at 5510. In the wake of the implementation of these standards, approximately 94% of HMIWI shut down and an additional 3% obtained exemptions from the regulations. *Id.* at 5518.

In February 2007, EPA finally issued a proposed rule in response to the 1999 remand. 72 Fed. Reg. at 5510. In this proposal, EPA offered a detailed rationale for its approach to determining the MACT floors. It identified and corrected errors in its previous methodology, which resulted in revised MACT floor determinations. The new floor determinations were based on much of the same data upon which EPA had relied in 1997, but the adjusted methodology “result[ed] in proposed emission limits that in many cases are more stringent than the limits promulgated in 1997.” In addition to undertaking revisions in response to this court’s remand, the EPA made further revisions in fulfillment of its obligation under the CAA to conduct a review of emissions standards every five years and revise the standards as necessary to keep them aligned with the statutory requirements. 72 Fed. Reg. at 5518; *see* §§ 7411(a)(1), 7429(a)(5). Specifically, in performing its five-year review it revised some of the emissions limitations “to reflect the actual performance of the MACT technologies” under the 1997 standards. 72 Fed. Reg. at 5533.

On December 1, 2008, the EPA issued a new proposed rule, declaring that “following recent court decisions and receipt of public comments regarding [the February 2007] proposal, we chose to re-assess our response to the Court’s remand.” 73 Fed. Reg. 72,962, 72,962 (Dec. 1, 2008). The EPA explained it no longer was confident that state regulatory limits were reasonable substitutes for actual emissions data. Because of this uncertainty combined with the unavailability of emissions data from the many units that had shut down in the wake of the 1997 requirements, EPA concluded that “the best course of action is to re-propose a response to the remand based on data from the 57 currently operating HMIWI.” *Id.* at 72,970. Although the EPA stated that this new proposed rule discharged its duty to perform a five-year review, it maintained that its recalculation of MACT floors was done pursuant to its duty to set emissions limitations in the first instance, not solely in fulfillment of its review duty under § 7429(a)(5).

The EPA issued its final rule on October 6, 2009. 74 Fed. Reg. at 51,368. The final rule used the same basic methodological approach as the 2008 proposal, with a few statistical adjustments that resulted in generally more stringent limits than had been previously proposed. In the final rule, the EPA for the first time removed the “startup, shutdown, and malfunction exemption” (“SSM exemption”), which had provided that no waste was counted against a unit during an SSM period.

This challenge followed the publication of the final rule. The Clean Air Act empowers us to reverse the Administrator’s action in rulemaking if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” § 7607(d)(9)(A); *see Bluewater Network v. EPA*, 370 F.3d 1, 11 (D.C. Cir. 2004) (noting that review under the CAA’s “arbitrary and capricious” standard is the same as review under the

7

Administrative Procedure Act, 5 U.S.C. § 706(2)(A)).

II.

A.

The petitioners contend that the EPA exceeded its authority under the Clean Air Act when it revised the HMIWI MACT floors based on data collected after implementation of the 1997 standards. It is undisputed that once the EPA has set the floors, it may thereafter establish standards more stringent than those floors. However, petitioners raise an objection to the standards established by the EPA after remand of the earlier decision. The objection is double faceted, but in both its aspects is based on the proposition that the CAA only authorizes a one-time establishment of floors based on the level of emission control “achieved in practice by the best controlled similar unit” for new units, and at “the average emissions limitation achieved by the best performing 12 percent of units in the category” for existing units. Petitioners’ first objection to the setting of the standards before us is that the EPA based its calculations not on the best performing 12 percent at the time of the original rulemaking, but rather on the best performing 12 percent of the remaining entities in the field after the shutdown of 97 percent of the units existing during the earlier proceeding. As the remaining units are the most efficient of the original group, the emissions levels upon which the EPA based its floor were ratcheted downward. Petitioners refer to this approach as “MACT-on-MACT.” That gives rise to the second facet of this argument. Petitioners contend that the new “floors” are in fact revised standards subject to the provisions of §§ 7411(a)(1) and 7429(a)(5), which require the EPA to consider the cost of compliance. Briefly put, petitioners contend that to set standards more stringent than floors based on the 1997 data, the EPA must consider cost and other factors listed in the statute—either as part of an initial

standard-setting process or as part of the five-year review.

Petitioners further argue that the remand in *Sierra Club-HMIWI* did not authorize the recalculation of the MACT floors. They argue that by remanding the standards without vacating, the court “affirmed the validity of the EPA’s 1997 data set.” The EPA, they contend, should have continued to use that data set in responding to the remand, as it did in its 2007 proposal. When the EPA chose instead to abandon that data set and rely on compliance data collected after the 1997 standards were implemented, it was acting outside the scope of the remand.

The EPA responds that nothing in the Clean Air Act or in the *Sierra Club-HMIWI* decision suggests that it is prohibited from resetting the MACT floors in order to correct its own errors. It suggests that the approach petitioners label “MACT-on-MACT” would be more accurately described as “MACT-on-Unsupportable-Standards-Erroneously-Labeled-as-MACT.” It insists that its action was a reasonable response to this court’s remand.

We agree with the EPA. Granted, its action was fraught with cunctation. The ten-year gap between our remand and the promulgation of the revised floors no doubt contributed to the unavailability of emissions data from a larger segment of the HMIWI units operating in 1997. The delay imposed protracted regulatory uncertainty on the industry, which continued to be subject to the 1997 standards while the agency dithered. But neither the length of the delay nor the problems caused by that delay affect the ultimate validity of the EPA’s product.

When this court remanded the 1997 standards without vacating them, we did not thereby affirm the data set the EPA had used to set those standards. We did not hold that the use of regulatory data to set MACT floors was “inherently

impermissible” under the statute, but instead left open the possibility that the use of such data might be acceptable “as long as it allows a reasonable inference as to the performance of the top 12 percent of units.” *Sierra Club-HMIWI*, 167 F.3d at 662-63. We most certainly did not mandate that EPA must proceed from the data set it had employed in the initial setting of the floors. Indeed, we withheld vacatur for the purpose of allowing the EPA an opportunity to establish the reasonableness of its then-current regulations. Had we been satisfied of the adequacy of the regulations and the data set on which the regulations were based, the remand would hardly have been necessary. As we stated at the time, “[i]t is possible that EPA may be able to explain [its methodology].” *Id.* at 664. We remanded so that the agency could attempt to do so. We declined to vacate the standards at the express request of the petitioner Sierra Club, which did not want the court to eliminate all federal control while the EPA determined its next step. *Id.*

In the course of revisiting its 1997 standards and attempting to arrive at a reasonable explanation for its action, the EPA came to believe that the approach it had taken in setting those standards was unsupportable. Far from being an inappropriate response to the remand, this is precisely the type of analytic assessment we expect an agency to conduct when its regulation has been remanded by a court. Once the EPA concluded that the regulatory data it had used in 1997 did not reliably approximate the emissions levels achieved in practice by best performing units, it rightly recognized that it could not continue to use that data set. By the time the EPA had identified the infirmities in its data set, it was no longer able to gather emissions data from the vast majority of HMIWI units operational at the time the original floors were promulgated. *See* 73 Fed. Reg. at 72,970. Therefore, it chose to use “the most reliable” data available: actual emissions levels from the 57 units remaining in operation. *Id.* This decision constituted a reasonable attempt at following

the statute's direction to set the MACT floors at a level achieved by the best performing units. It was also well within the scope of the remand.

At oral argument, counsel for the petitioners affirmed that they would not be challenging EPA's decision to reset the floors as so-called MACT-on-MACT if the court had vacated the standards at the time of remand, because in that case the agency would be regulating on a blank slate. We are not persuaded that remand without vacatur as opposed to vacatur has the outcome-changing significance the petitioners ascribe to it. Although in *Sierra Club-HMIWI* we did not vacate the standards, we made clear that we had serious concerns about their validity. The standards remained in place, but they had not been accepted by the court as fulfillment of the agency's duty under the Clean Air Act to set emissions levels.

Sierra Club-HMIWI left open the question whether the EPA could offer a reasonable explanation for its use of the regulatory data in its initial determination. On remand, the EPA determined that it could not. When the EPA determined that its regulation rested on unreliable data and that it had to reset the floors, the agency was functionally regulating on a blank slate even though the regulation continued to remain on the books. Therefore, the emissions levels contained in the new rule are properly characterized not as "beyond-the-floor," or as a revision conducted as part of the five-year review, but as the floor-setting that is the initial step in establishing emissions standards. *See* 42 U.S.C. § 7429(a)(2), (5). The former require consideration of the costs of compliance, but the latter does not. *Id.* We hold that, given this court's previous remand without vacatur and the agency's subsequent determination that it was unable to provide a rational explanation for continued use of the data upon which it had relied, the EPA acted lawfully in resetting the MACT floors based on post-compliance emissions

data.

B.

The petitioners' second challenge is to the EPA's "pollutant-by-pollutant" approach to setting MACT floors. In other words, the petitioners are challenging EPA's interpretation of the statutory requirement that it determine the level of emissions control achieved by "the best controlled similar unit" to permit it to identify a top-performing unit (or units, when setting standards for existing HMIWI) for each individual pollutant, rather than one unit that is the best controlled overall. *See* § 7429(a)(2). The result, petitioners argue, is that the floors are set with reference to "a hypothetical 'super unit'" that attains maximum emissions control for every pollutant. The petitioners insist that EPA's approach, and the resulting floors, violate the CAA because these floors have never been "achieved in practice" by any single unit.

We will not reach the merits of this challenge. Petitioners' claim is barred by 42 U.S.C. § 7607(b)(1). That provision directs that any petition for review must be filed within sixty days from the date that notice of the challenged action appears in the Federal Register. The filing period in the Clean Air Act "is jurisdictional in nature," *Motor & Equip. Mfrs. Ass'n v. Nichols*, 142 F.3d 449, 460 (D.C. Cir. 1998) (internal quotation marks omitted); if the petitioners have failed to comply with it, we are powerless to address their claim. Petitioners did in fact fail to comply.

EPA used the same pollutant-by-pollutant approach to set the standards in its 1997 rule. *See* 62 Fed. Reg. at 48,363-64. Although this approach was questioned by commenters (and EPA responded to those comments in its final rule), *see id.*, no one challenged the pollutant-by-pollutant approach in court at

that time. The sixty-day window provided by statute has long since closed, and we may not reopen it and entertain a belated challenge to the EPA's pollutant-by-pollutant approach now. The petitioners point out that they lodged objections to the approach during the rulemaking that culminated in the 2009 final rule, *see* 74 Fed. Reg. at 51,380-82, in compliance with the statutory requirement that objections must be "raised with reasonable specificity during the period for public comment" in order to be preserved for judicial review. *See* § 7607(d)(7)(B). While this is true, a renewed objection before the agency does not compensate for the petitioners' failure to raise their complaint before the court within sixty days of the EPA's first use of the pollutant-by-pollutant approach, as required by the statute. Nor does the EPA's defense of the methodology in its comments demonstrate it actually or constructively reopened the issue. *See Am. Road & Transp. Builders Ass'n v. EPA*, 588 F.3d 1109, 1115 (D.C. Cir. 2009). The petitioners' challenge to the EPA's longstanding practice of setting floors based on the emissions levels achieved by the best performing units with respect to each individual pollutant is barred.

C.

The petitioners' final challenge is to the EPA's removal of a provision exempting HMIWI from meeting emissions standards during periods of startup, shutdown, or malfunction ("SSM"). The SSM exemption had appeared in the 1997 rule, and was retained in the 2007 proposal and 2008 re-proposal. *See* 74 Fed. Reg. at 51,375. But in the 2009 final rule, the EPA announced its decision to remove the exemption and make the emissions limits applicable at all times. *Id.* The EPA grounded its action in this court's *Sierra Club v. EPA* ("*Sierra Club-SSM*") opinion, published after the 2008 proposal issued, which vacated provisions (promulgated under a different section of the CAA) exempting "major sources of air pollution" from

following normal emissions standards during SSM periods. 551 F.3d 1019, 1021 (D.C. Cir. 2008). Although the EPA recognized that the *Sierra Club-SSM* decision did not directly impact the HMIWI standards at issue in the rulemaking then underway, it concluded that “the legality of source category-specific SSM provisions such as those adopted in the 1997 HMIWI rule [was] questionable” in the wake of the court’s opinion. *See* 74 Fed. Reg. at 51,394. In addition, it determined that “the exemption and definitions as promulgated in 1997 provided virtually no utility” to HMIWI units. *Id.* Petitioners argue that the EPA’s decision to remove the SSM exemption was arbitrary and capricious.

Again the petitioners have failed to comply with a procedural prerequisite for judicial review. The Clean Air Act instructs that:

Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed.

§ 7607(d)(7)(B). Petitioners did not raise their objection to the removal of the SSM exemption before the agency with reasonable specificity. Petitioners correctly point out that

because the first indication from the agency that it would remove the exemption was in the final rule, they did not have a provocation or an opportunity to object to the removal during the comment period. But the statute provides for just such a situation by offering an alternative way to present an objection to the agency in order to tee it up for judicial review. It requires an interested party unable to raise its objection during the comment period to file a motion for reconsideration. Petitioners did not do so, and “[p]etitioners who fail to comply with this exhaustion requirement are barred from seeking judicial review.” *Nat’l Ass’n of Clean Air Agencies v. EPA*, 489 F.3d 1221, 1231 (D.C. Cir. 2007). We will not review the petitioners’ challenge to the EPA’s decision to remove the SSM exemption from the final rule.

III.

We hold that the EPA’s decision to use emissions data from the HMIWI units remaining in operation after the implementation of the 1997 standards, once it determined that the data set upon which it had relied in 1997 was flawed, was reasonable. We do not have jurisdiction to review the challenges to the EPA’s long-standing practice of setting emissions floors based on emissions levels achieved by the best performing unit or units for each individual pollutant, and to the agency’s removal of an exemption from compliance with emissions limitations during periods of startup, shutdown, and malfunction.

The petition is dismissed in part and denied in part.