IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MEDICAL WASTE INSTITUTE and ENERGY RECOVERY COUNCIL,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

No. 09-1297

Petition for Review of Final Administrative Action
of The United States Environmental Protection Agency

EPA'S RESPONSE TO PETITION FOR REHEARING *EN BANC*

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GLOSSARY

CAA	Clean Air Act, 42 U.S.C. §§ 7401-7671q
EPA	United States Environmental Protection Agency
HMIWI	Hospital/Medical/Infectious Waste Incinerators
MACT	Maximum achievable control technology
Pet. Br.	Petitioners' Brief to the Panel
Pet. Reply Br.	Petitioners Reply Brief to the Panel
Rehearing Pet.	"Petition of Medical Waste Institute and Energy Recovery Council for Rehearing or Rehearing *en Banc*"*****

Key Rulemakings:

1997 Rule	62 Fed. Reg. 48,348 (Sept. 15, 1977)
2009 Rule	74 Fed. Reg. 51,368 (Oct. 6, 2009)

JURISDICTIONAL NOTE

***** The Court's Order requested that EPA respond only to the Petition for Rehearing *En Banc*. Accordingly, EPA has not responded to "Intervenor-Petitioners' Petition for Panel Rehearing" (Dkt. 1323131).

INTRODUCTION

In its 1997 regulation governing air pollutant emissions for Hospital/Medical/Infectious Waste Incinerators ("HMIWI" or "medical incinerators"), the Environmental Protection Agency ("EPA") established emissions floors for the nine separate pollutants regulated under 42 U.S.C. § 7429(a)(4). In utilizing those floors to establish minimum emission standards, which were statutorily required to be based on emissions levels actually achieved by the best performing HMIWI units, EPA made it clear that they were set on a pollutant-by-pollutant basis (i.e., based on emissions levels achieved by the best performing unit for *each* of the nine pollutants), rather than on a single incinerator that performed the best with regard to all nine pollutants considered together (the "single unit" approach).

In 1999, this Court held that the specific numeric emission floors established in the 1997 regulations could not be legitimately supported by the data relied upon by EPA. Sierra Club v. EPA, 167 F.3d 658 (D.C. Cir. 1999) ("Sierra Club-HMIWI"). It did not, however, invalidate EPA's pollutant-by-pollutant approach to setting these standards. In 2009, EPA issued the regulation challenged in this case, resetting those numeric standards. 74 Fed. Reg. 51,368 (Oct. 6, 2009) (the "2009 Rule"). While EPA based its 2009 standards on more reliable emissions data from the best-performing units, it did not change or reconsider *in any way* its original determination that, regardless of the data set relied upon, emission standards would be established on a pollutant-by-pollutant basis.

Petitioners challenged EPA's use of revised data to set the emissions standards in the 2009 rule, a challenge Petitioners lost *on the merits*. Now, Petitioners attempt to resurrect their lost merits challenge by creating a fiction: that EPA's use of more reliable *data* somehow altered EPA's *methodology* in setting the emissions floors on a pollutant-by-pollutant basis. EPA's pollutant-by-pollutant approach to setting these standards was challenged in the comments on the 1997 Rule, addressed by EPA in the preamble to that Rule, expressly adopted by EPA in the 1997 Rule, and strictly adhered to in the 2009 Rule. Petitioners may not rely on semantic gymnastics in defining "methodologies" and "standards" to reopen an issue that was expressly addressed and decided in a prior regulation and not revisited in the new regulation.

STAUTORY AND REGUALTORY BACKGROUND

Pursuant to 42 U.S.C. § 7429, EPA sets emissions standards for, among others, medical incinerators, for nine specified pollutants. Emissions of these nine pollutants can be reduced through various mechanisms, including "control technologies" (e.g., scrubbers), "combustion control" (proper design and operation of an incinerator), and "waste segregation" (separation of certain waste prior to incineration). 74 Fed. Reg. at 51,369. EPA does not direct a source to install particular types of control technologies, combustion controls, or mechanisms for removing waste. Instead, EPA *must* promulgate the standards for each listed pollutant as individual numeric emission limits, which medical incinerators can then meet through any means they choose. 42 U.S.C. § 7429(a)(4).

Because EPA's standards are based in part on implementation of "maximum achievable control technology," the numeric standards EPA establishes commonly are referred to as "MACT." EPA's individual MACT standards must, *at a minimum*, reflect the emission limitations that EPA identifies as the "floor." 42 U.S.C. § 7429(a)(2). Floors for new units must reflect emissions reductions that are "achieved in practice by the best controlled similar unit," while the floors for existing units "shall not be less stringent than the average emissions limitation achieved by the best performing 12 percent of units in the category . . . ." Id.

On September 15, 1997, EPA issued its initial individual numeric MACT standards for medical incinerators. 62 Fed. Reg. 48,348 (Sept. 15, 1997) ("1997 Rule"). Although the MACT floors were expressly required by 42 U.S.C. §7 429(a)(2) to be based on the emissions limitations actually achieved by the best-performing medical incinerators, in 1997 there existed a lack of data reflecting the emissions limitations achieved by those units. 72 Fed. Reg. 5510, 5513 (Feb. 6, 2007). Accordingly, EPA used a surrogate, basing the floors on the emissions it projected medical incinerators would have achieved if they complied with the panoply of applicable state regulations, supplemented with data from tests performed on medical incinerators that employed *no* pollution controls. 62 Fed. Reg. at 48,352.

Utilizing this surrogate, EPA set individual MACT floors for new and existing units for each of the nine covered pollutants. EPA based the emission standards on the limitations EPA then estimated were *actually achieved* on a *pollutant-by-pollutant* basis.

62 Fed. Reg. at 48,363-64; Rehearing Pet. 3. Commenters asserted that EPA should not determine floors on a pollutant-by-pollutant basis but instead should base them on the emissions of all covered pollutants that could then be achieved by a single unit. 62 Fed. Reg. at 48,363. EPA responded to this assertion in detail.

First, EPA stated that it "recognizes that the pollutant-by-pollutant approach for determining the MACT floor can, as it does in this case, cause the overall cost of the regulation to increase." Id. Thus, EPA acknowledged that regulated entities had a significant incentive to challenge the pollutant-by-pollutant approach. Then, recognizing ambiguity in the statute, EPA applied the pollutant-by-pollutant approach that it believed Congress had intended:

> EPA interprets section 129 of the CAA to require that the MACT floor be determined in this [pollutant-by-pollutant] manner, and EPA believes that Congress did in fact intend that sources subject to regulations developed under section 129 meet emission limits that are achieved by the best controlled unit for each pollutant . . . . EPA does not agree that the MACT floors are to be based on one overall unit. Rather, the EPA believes that section 129 supports its interpretation that it is legally permissible to set the MACT floor pollutant-by-pollutant . . . . The fact that Congress singled out these pollutants suggests that the floor level of control need not be limited by the performance of devices that only control some of these pollutants well.

Id. at 48,363-64 (also referring to the "discussion of the legal basis for the pollutant-by-pollutant approach" contained in its 1997 Comment Response document).

Although a Petition for Review was filed challenging the 1997 Rule, and industry representatives, *including Petitioners in this case*, participated in that action, *no one* challenged EPA's pollutant-by-pollutant approach for identifying the MACT floors.

Rehearing Pet. 4, 6. Acting on the Petition, in 1999 this Court remanded the 1997 emissions standards. The Court did not address the pollutant-by-pollutant approach because it had not been challenged. Instead, the Court found that under that approach, the individual emission levels set by EPA could not be supported because the surrogate data it relied upon to set the numeric floor for each pollutant did not appear to reflect the actual individual pollutant emission levels being achieved by the best performing sources. Sierra Club-HMIWI, 167 F.3d at 662-64. The Court remanded the matter to EPA to either better explain how its surrogate accurately reflected actual emissions or utilize more reliable data.

By the time EPA issued the revised emissions floors in its 2009 Rule, it possessed data reflecting the *actual* emissions from medical incinerators. Thus, the 2009 Rule set the MACT floors based on new and more accurate data: the data reflecting emissions levels actually achieved by the best-performing sources for each pollutant. 74 Fed. Reg. at 51,378-79. It is undisputed that in revising the MACT floors, EPA adhered to the *identical* methodology of determining floors pollutant-by-pollutant it had adopted in 1997. Rehearing Pet. 8 ("EPA still interpreted the CAA as supporting a 'pollutant-by-pollutant' approach . . . ."). Absolutely nothing changed about EPA's use of a pollutant-by-pollutant approach to determine floors or its unchallenged 1997 interpretation of 42 U.S.C. § 7429 as directing this approach.

Addressing Petitioners' arguments for reopening the pollutant-by-pollutant issue, this Court explained that "EPA used the same pollutant-by-pollutant approach

to set the standards in its 1997 rule" that it used in the 2009 Rule and there was no basis to reopen this issue, either "actually or constructively." Medical Waste Inst. v. EPA, 645 F.3d 420, 427 (D.C. Cir. 2011). Contrary to Petitioners' assertion, the Court did *not* "consider[] only whether comments on the 2008 proposal and EPA's responses thereto 'actually or constructively reopened the issue.'" Rehearing Pet. 7. The Court merely articulated this point because Petitioners had asserted, among other things, that by responding to comments in the 2009 Rule on the pollutant-by-pollutant approach, EPA had reopened the issue.

ARGUMENT

I. NOTHING ABOUT EPA'S POLLUTANT-BY-POLLUTANT METHODOLOGY CHANGED IN THE 2009 RULE

Petitioners premise their reopener argument on the assertion that because "EPA *revised its overall methodology* in setting the floors, the matter was no longer 'settled,' and it was incumbent upon EPA to obtain comment on all aspects of this methodology," contending that this puts the Panel's ruling in conflict with this Court's decision in Kennecott Utah Copper Corp. v. Dep't of Interior, 88 F.3d 1191, 1213 (D.C. Cir. 1996). Rehearing Pet. 13 (emphasis added). Petitioners' assertion is, however, based on a fictional description of EPA's actions. In fact, *nothing* about EPA's pollutant-by-pollutant approach changed between the 1997 Rule and the 2009 Rule. The only changes in EPA's application of the statute concerned data issues:

data selection, which Petitioners challenged in 2009 and lost; and rounding and statistical data distribution, which Petitioners have not challenged.

Petitioners admit that in 1997 EPA based the MACT floors on the lowest emissions assumed to have been achieved for "each pollutant." Rehearing Pet. 8. Petitioners further concede that in the 2009 Rule "EPA still interpreted the CAA as supporting a 'pollutant-by-pollutant' approach" and applied that identical approach. Id. And Petitioners do not dispute that in each case, EPA was required to set the individual pollutant numeric emissions standards (derived from their floors) based on the best performing units. Rather, Petitioners assert that because EPA based the revised standards on more reliable data than was available in 1997, EPA somehow created a *new* pollutant-by-pollutant methodology that may now be challenged. Id.

As Petitioners *themselves* explained to the Panel, the 1997 MACT standards reflecting the emissions levels actually achieved by the best-performing HMIWI were remanded by this Court because those standards were based on unreliable surrogate *data – not* because of any legal defect in the pollutant-by-pollutant approach EPA used in setting those standards. Pet. Br. 8, 10, 13, 15, 17, 18, 19, 20, 21, 22, 23, 24, 35; Pet. Reply Br. 1, 3, 4, 5, 6, 7, 8, 9, 10. In the 2009 Rule, EPA simply reset those standards based on new data (actual emissions, rather than a surrogate) comporting with this Court's decision. Petitioners challenged EPA's use of actual emissions data to support the 2009 standards, a challenge that was considered by this Court on the merits and rejected. Medical Waste, 645 F.3d at 426. Petitioners now attempt to use

the very same rejected complaint about EPA's reliance on actual emissions *data* to assert that EPA's pollutant-by-pollutant *methodology* changed in the 2009 Rule.

Specifically, Petitioners assert that EPA changed its pollutant-by-pollutant methodology because in 2009 EPA supposedly set the revised emissions standards "irrespective of the control technologies used to achieve the emission reductions for each pollutant." Rehearing Pet. 5-6. First, this is an argument that Petitioners never raised before the Panel as a basis for reopener and therefore certainly cannot be considered for the first time in an *En Banc* Petition. Moreover, this assertion is facially incorrect. The 2009 numeric emissions standards are based on actual emissions levels achieved by the best performing sources. As noted above, control technologies are one of three methods of reducing emissions – in fact the key method, in the case of medical incinerators. Thus, the actual emissions levels achieved by the best performing sources (which formed the basis of the 2009 floors), were *based on* the use of control technologies; they were not issued *irrespective* of those technologies. Indeed, under Petitioners' reasoning, the 1997 floors also were set "irrespective of control technologies," because they were based in part on test data from units employing no control technologies whatsoever. See supra p. 3.

Most importantly, the only thing that changed between 1997 and 2009 was, in addition to rounding and statistical adjustments that Petitioners have not challenged, the data used to determine the source that actually achieved the lowest emission level for each covered pollutant and what that level was. For example, in 1997, EPA set the

emission floor for dioxin based on a single unit (or 12% of units for existing sources) that achieved the lowest emissions for dioxin, regardless of how that source(s) performed with regard to the other eight covered pollutants. In 2009, EPA applied the *exact same* approach: EPA set the emission standard for dioxin based on the unit that achieved the lowest emissions for dioxin, regardless of how that unit performed with regard to the other eight covered pollutants. The only difference is how EPA measured precisely how low that individual pollutant's emissions level was: in 1997, EPA based that level on *surrogate* emissions data; in 2009, EPA based it on *actual* emissions data.

Petitioners complain that under the 2009 Rule a unit might be the best performing for one pollutant but the worst performing for another pollutant and that this was a new concept that they did not have an opportunity to challenge in the 1997 rule. Rehearing Pet. 8. But this is not a new concept at all, as this *precise* criticism applied equally to the pollutant-by-pollutant approach applied by EPA in 1997, where certain floors reflected use of controls at some sources that regulated particular pollutants well while those same sources may have performed poorly as to other covered pollutants. See e.g., 62 Fed. Reg. at 48,363-64. Thus, the pollutant-by-pollutant approach utilized by EPA in the 2009 Rule did not "significantly change how the standards were set," as Petitioners' assert; rather, it applied the *identical* pollutant-by-pollutant approach to re-set, based on better data, the revised individual pollutant numeric standards required by the statute.

II. A PARTY MAY NOT CHALLENGE ALL PRIOR AGENCY DETERMINATIONS WHENEVER AN EMISSION STANDARD IS REVISED

Petitioners contend that in order for their challenge to the 2009 standards to be meaningful, they must be permitted to challenge the pollutant-by-pollutant methodology first applied by EPA in 1997. Rehearing Pet. 9. Petitioners assert that, because it is merely a "methodology," EPA's longstanding pollutant-by-pollutant approach is *always* open to new attack, *every time* EPA revises standards, even if the methodology itself never changes. Id. at 10. These arguments contradict the very purpose of 42 U.S.C. § 7607(b)(1) and Plaintiffs fail to cite to any case even implying that revising numerical standards provides an automatic trigger to reopen all prior agency determinations under a regulatory program.

As the Panel's decision noted, the bar of § 7607(b)(1) "is jurisdictional in nature and may not be enlarged or altered by the courts." 645 F.3d at 427 (citation omitted). An agency determination reached in a prior rulemaking can be reopened only if the agency expressly reopens it or consciously acts to "reexamin[e] … the *policy* at issue in the petition." Nat'l Mining Ass'n v. Dep't of Interior, 70 F.3d 1345, 1351 (D.C. Cir. 1995) (emphasis added) (an agency's statement of "renewed adherence" to the former determination does not reopen the issue). See also P & V Enters. v. U.S. Army Corps of Eng'rs, 516 F.3d 1021, 1024 (D.C. Cir. 2008). Discussion in the preamble to the new regulation of the issue decided in the earlier regulation does not constitute reopening, Am. Iron & Steel Inst. v. EPA, 886 F.2d 390, 398 (D.C. Cir. 1989), nor

does the act of responding to unsolicited comments. Kennecott Utah Copper Corp. v. Dep't of Interior, 88 F.3d at 1213; Am. Road & Transp. Builders Ass'n v. EPA, 588 F.3d 1109, 1114-15 (D.C. Cir. 2009), cert. denied, 131 S. Ct. 388 (2010). If the agency does not affirmatively seek comment on the *specific* established policy being challenged, or otherwise affirmatively reconsider *that* policy, challenges to the policy announced in the earlier regulation are barred. Id.; NRDC v. EPA, 571 F.3d 1245, 1265-66 (D.C. Cir. 2009); EDF v. EPA, 467 F.3d 1329, 1333 (D.C. Cir. 2006).[1]

In this case, EPA merely went back and examined new data to be used in setting the MACT floors. Petitioners challenged EPA's use of that data, which this Court addressed on the merits. EPA never, however, asked for comment on, consciously reconsidered, or otherwise reopened the longstanding pollutant-by-pollutant aspect of the methodology it used to set the emission floors.

Petitioners cannot circumvent the jurisdictional bar of § 7607(b)(1) by asserting that regulated entities can only challenge regulations, and so every time a regulation is issued all previously decided rulings relating to the challenged regulation are open to attack. Rehearing Pet. 10. If an agency issues revised standards, those standards can be challenged on their merits, as they were (unsuccessfully) here. Such a challenge

[1] Petitioners' citation to Montana v. Clark, 749 F.2d 740 (D.C. Cir. 1984) is inapposite. There, the central issue was whether the new regulation was a final order subject to judicial review. There is no dispute that the 2009 Rule was a final order. Beyond that, the agency in Montana affirmatively revaluated "the entire substance of the regulation," id. at 744, which clearly did not happen here.

does not, however, reopen regulatory approaches and interpretations decided long ago, even if they underlie the revised standards. See, e.g., NRDC v. EPA, 571 F.3d at 1265 (allowing petitioners to challenge the elimination of the attainment requirement for emission offset credits promulgated in the new regulation but "reject[ing] as untimely the NRDC's challenge to the general [long-standing] policy of allowing pre-application offset credits."); EDF v. EPA, 467 F.3d at 1334 ("We require evidence that an interpretation adopted by EPA prior to the 2004 rulemaking differed from its own current interpretation.").

Petitioners contend there would have been no case or controversy in 1997 if they had then attempted to challenge EPA's pollutant-by-pollutant approach. Rehearing Pet. 11. This is again facially incorrect. As EPA stated in 1997, the pollutant-by-pollutant approach was not clearly compelled from the face of the statute and thus the Agency exercised its discretion in concluding that the best reading of the statute called for a pollutant-by-pollutant approach. 62 Fed. Reg. at 48,363-64. Clearly, when an agency interprets how a statute is to be applied in such circumstances that impose binding, enforceable requirements in the form of numeric standards, a case or controversy exists. Indeed, that controversy is exhibited in the comments to the 1997 Rule objecting to the pollutant-by-pollutant approach. Petitioners' "new" argument that the pollutant-by-pollutant approach "is inconsistent with the plain language of the CAA," Rehearing Pet. 13, certainly is one that could have been made in 1997, when EPA expressly interpreted the disputed provision.

Finally, there is no basis to reopen an issue because Petitioners claim that the issue is of "exceptional importance" or is "broadly applicable." Rehearing Pet. 10. While exceptional importance may be a basis for hearing an issue *en banc* under Fed. R. App. P. 35 when the Panel has actually addressed that substantive issue, this Court has never found that a litigant may use Rule 35 and its reference to exceptional importance of an issue as a license to circumvent the jurisdictional bar of § 7607(b)(1). Moreover, the pollutant-by-pollutant issue is hardly of exceptional importance; it applies only to the remaining 57 medical incinerators (compared to 2,400 in 1997). The fact that there are *other* industries governed by *other* MACT regulations does not cure Petitioners' failure to have challenged EPA's adoption of the pollutant-by-pollutant approach *for medical incinerators* in 1997.

III. THERE WAS AMPLE INCENTIVE TO CHALLENGE THE POLLUTANT-BY-POLLUTANT APPROACH UTILIZED IN THE 1997 RULE AND THE PANEL'S DECISION DOES NOT CONFLICT WITH THE LAW OF THIS CIRCUIT

Petitioners assert that "industry had no incentive to challenge the prior [1997] standards," that the 2009 Rule "significantly alter[s] the stakes for seeking judicial review," and therefore, the Panel's holding here is inconsistent with this Court's decisions regarding constructive reopening, citing Kennecott, 88 F.3d 1191. Rehearing Pet. 1, 11, 13. It is Petitioners, however, who misapply this Court's precedent and simply ignore the markedly greater incentive that existed in 1997.

As this Court has explained, "' [a] constructive reopening occurs if the revision of accompanying regulations "significantly alters the stakes of judicial review" as the result of a change that "could have not been reasonably anticipated," such that it affects a "sea change" in the manner in which the regulatory scheme works. NRDC v. EPA, 571 F.3d at 1266 (quoting Sierra Club v. EPA, 551 F.3d 1019, 1025-26 (D.C. Cir. 2008) and Kennecott, 88 F.3d at 1214). In applying this rule, "Petitioners have [the] burden of proving that EPA either changed the regulatory context in such a way that could not have been reasonably anticipated . . . or officially reinterpreted the regulation." EDF v. EPA, 467 F.3d at 1334 (citations omitted).

First, Petitioners' incentive to challenge the 1997 pollutant-by-pollutant approach was overwhelmingly clear at that time. EPA specifically noted that its pollutant-by-pollutant approach would cost HMIWI more money than the single unit approach. 62 Fed. Reg. at 48,363. Thus, EPA expressly informed industry of its incentive to challenge this approach in 1997. Moreover, according to *Petitioners*, the 1997 Rule, with its pollutant-by-pollutant approach, "caused the shutdown of 98% of the industry." Pet. Br. 5 (see also p. 18, explaining how the 1997 standards "resulted in almost a complete shutdown of the medical incinerator industry"). Thus, the 2009 Rule hardly "alter[ed] the stakes of judicial review." NRDC v. EPA, 571 F.3d at 1266.

Additionally, as noted, in 1997 the emissions floors were set on a pollutant-by-pollutant basis using *surrogate* data to determine the actual emission levels being

achieved. In 2009, the emissions floors were based on the identical pollutant-by-pollutant approach, this time based on *actual* emissions data in setting the numerical standard for each pollutant. Clearly, the 2009 Rule "did not work such a sea change. The basic regulatory scheme remains unchanged." 571 F.3d at 1266. Neither was the use of a pollutant-by-pollutant approach in 2009 unanticipated, since that is precisely the approach used in 1997. The Panel's holding is clearly consistent with this Court's decisions on actual *and* constructive reopening.

Finally, Petitioners assert that "[f]or units not in existence at the time of the prior rule, any challenge to the methodology would be barred." Rehearing Pet. 12. That is exactly right. An agency's determinations and methodologies that have been subjected to comment, set forth in a final rule that is subject to court challenge, and thereafter barred under 42 U.S.C. §7607(b)(1), cannot then be reopened every time a new entity starts business in the affected industry. Such businesses are charged with knowing the state of the law when they initiate their business and may not be used as a conduit for the industry to challenge anew prior agency determinations.

CONCLUSION

For the foregoing reasons, the Petition for Rehearing *En Banc* should be denied.

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing EPA's Response to Petition for Rehearing *En Banc*, was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of said filing to the attorneys of record for Petitioners and all other parties who have registered with the Court's CM/ECF system.

Date: September 29, 2011

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