United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 3, 2001 Decided May 17, 2002

No. 00-1394

General Electric Company,
Petitioner

v.

Environmental Protection Agency,
Respondent

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

Angus Macbeth argued the cause for petitioner. With him on the briefs were Patricia K. Casano, Christopher L. Bell and Timothy K. Webster.

H. Michael Semler, Attorney, U.S. Department of Justice, argued the cause and filed the briefs for respondent.

Before: Ginsburg, Chief Judge, and Randolph and Tatel, Circuit Judges.

Opinion for the Court filed by Chief Judge Ginsburg.

Ginsburg, Chief Judge: General Electric Co. petitions for review of the "PCB Risk Assessment Review Guidance Document" issued by the Environmental Protection Agency. The parties dispute (1) whether this case is ripe for review; (2) whether the Document is a "rule" within the meaning of s 19(a) of the Toxic Substances Control Act (TSCA), and hence whether the court has jurisdiction to review its promulgation; and (3) whether the Agency should have followed the procedures required for rulemaking in the TSCA and in the Administrative Procedure Act when it promulgated the Document. We conclude that the case is ripe for review, and that the Guidance Document is a legislative rule such that the court does have jurisdiction to entertain GE's petition and the Document should not have been issued without prior notice and an opportunity for public comment.

I. Background

The TSCA prohibits the manufacture, processing, distribution, and use (other than in a "totally enclosed manner") of polychlorinated biphenyls (PCBs) unless the EPA determines that the activity will not result in an "unreasonable risk of injury to health or the environment." 15 U.S.C. s 2605(e)(2) & (3). The Guidance Document governs the application of two regulations promulgated by the EPA under the TSCA to provide respectively for the cleanup and disposal of PCB remediation waste and for the disposal of PCB bulk product waste. See 40 C.F.R. ss 761.61 ("cleanup and disposal options for PCB remediation waste"), 761.62 (how "PCB bulk product waste shall be disposed").

Under subsection (c) of each regulation a party may apply for permission to use a method other than one of the generic methods set out in the regulations for sampling, cleaning up, or disposing of PCB remediation waste, or for sampling or disposing of PCB bulk product waste. The EPA will approve applications under these subsections if the alternative method proposed does "not pose an unreasonable risk of injury to health or the environment." Id. The regulations do not,

however, tell applicants how to conduct the necessary risk assessment.*

That is where the Guidance Document comes in. It "provide[s] an overview of risk assessment techniques, and guidance for reviewing risk assessment documents submitted under the final PCB disposal rule." Guidance Document at 10. Of particular relevance to this case, in the Guidance Document the EPA also explains that an applicant seeking to use an alternative method under s 761.61(c) may take either of two approaches to risk assessment. Id. at 21, 42. First, the applicant may calculate cancer and non-cancer risks separately. Id. To calculate cancer risks the applicant would have to use a cancer potency factor recognized by the EPA. Such cancer potency factors range, depending upon the exposure pathway and upon the composition of the PCB mixture, from .04 to 2.0 (mg/kg/day)-1. Id., Table 9, at 64. To calculate the non-cancer risks a different type of toxicity value--a reference dose, for example--would have to be used, and certain specified non-cancer risks would have to be taken into account. Id. at 21, 42.

The second approach endorsed in the Guidance Document is to use a "total toxicity factor" of 4.0 (mg/kg/day)-1 to account for cancer and non-cancer risks together. Id. In its brief the EPA explains that this approach "provides the applicant an opportunity to reduce the time and expense associated with the risk assessment" because the Agency is willing "to accept this 'default' toxicity value of 4.0 (mg/kg/day)-1[ ] without requiring further justification."

II. Analysis

GE's primary argument is that the Guidance Document is a legislative rule and therefore should have been promulgated only after public notice and an opportunity for comment. In

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* The Guidance Document initially says it applies to both s 761.61 and s 761.62. See Guidance Document at 10. Later in the Guidance Document the EPA appears to use s 761.61 as shorthand for both provisions. See id. at 21. We follow the Agency's lead in referring henceforth only to s 761.61.

the alternative it contends that the Guidance Document is not supported by substantial evidence. Before considering these arguments about the merits, however, we must determine whether the case is ripe for review and whether we have jurisdiction to hear it.

A. Ripeness

To determine whether a controversy is ripe for judicial review the court must evaluate "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967). "In determining the fitness of an issue for judicial review we look to see whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." Clean Air Implementation Project v. EPA, 150 F.3d 1200, 1204 (D.C. Cir. 1998).

Here the EPA argues that "GE's claims satisfy neither aspect of the 'fitness'/'hardship' standard under Abbott Laboratories." Regarding fitness, the EPA argues that (1) GE is asking the court to consider factual questions, such as how the EPA would evaluate an application that did not use either of the approaches to toxicity set out in the Guidance Document; (2) the Guidance Document is not final agency action because the Agency "is currently conducting an assessment of the non-cancer risks of PCBs" and will be modifying the Document "as needed"; (3) "the Court's consideration would be aided by further application of the agency's position to particular facts"; and (4) judicial review is premature because "adjudication may well prove unnecessary."

We think the issues presented are fully fit for review. First, whether the Guidance Document is a legislative rule is largely a legal, not a factual, question, turning as it does in this case primarily upon the text of the Document. GE does rely in part upon the Agency's application of the Guidance Document, but we need not reach that issue; we hold the Guidance Document is a legislative rule because on its face it purports to bind both applicants and the Agency with the force of law.

Second, it is clear that the Guidance Document is final agency action because it marks the consummation of the EPA's decisionmaking process and it determines the rights and obligations of both applicants and the Agency. See Bennett v. Spear, 520 U.S. 154, 178 (1997). The EPA argues that the Guidance Document is not final because it is subject to change and the "EPA has not completed its decisionmaking process regarding the non-cancer impacts of PCBs." We rejected a similar argument in Appalachian Power Co. v. EPA, 208 F.3d 1015 (2000), stating: "The fact that a law may be altered in the future has nothing to do with whether it is subject to judicial review at the moment." Id. at 1022. If the possibility (indeed, the probability) of future revision in fact could make agency action non-final as a matter of law, then it would be hard to imagine when any agency rule--and particularly one that must be updated periodically to reflect advances in science--would ever be final as a matter of law.

In the same vein, the EPA contends that the Fifth Circuit's decision in Central & South West Services, Inc. v. EPA, 220 F.3d 683, 695 (2000), remanding the Final Rule governing PCB remediation and decontamination--which Rule the Agency promulgated using the 4.0 (mg/kg/day)-1 toxicity factor--was "[i]n effect" a decision that the case was "not ripe because EPA's position on this complex scientific issue was not final." But the court there did not purport in the least to hold GE's petition non-ripe or the Agency's Final Rule non-final. Id. Rather, the court remanded the issue without considering the merits of GE's petition because, in view of the EPA's continuing assessment of the toxicity of PCBs, the Agency had "no objection to a remand," and that was all the relief GE was seeking. Id.*

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* This is all the Fifth Circuit had to say:

> EPA is in the process of conducting a comprehensive assessment of the non-cancer toxic effects of PCBs. According to EPA, it promulgated the Final Rule before the assessment was completed, in order to comply with the desires of the regulated community to finalize the rulemaking as soon as possible. However, EPA states that it has already committed to reexam-

Third, we do not think "the Court's consideration would be aided by further application of the agency's position to particular facts." We conclude below that the Guidance Document should not have been issued without public notice and an opportunity for comment because the Document purports on its face to bind both applicants and the Agency. In this situation, nothing would be gained from delaying review.

The EPA's final argument regarding the fitness of the issues for review is that, if the court does not resolve this case now, then it may never be necessary to decide the underlying controversy. This contention rests upon the EPA's assertion that it will apply the Guidance Document flexibly. That assertion, however, simply restates a portion of the Agency's argument that the Document is not binding, an argument we reject below.

As for hardship, the EPA argues that GE will not be harmed if the court defers review of the Guidance Document because GE can later challenge under the APA any decision of the EPA denying its application for a risk-based alternative. As we have previously explained, however, "[w]here the first prong of the [Abbott Laboratories] ripeness test is met and Congress has emphatically declared a preference for immediate review ... no purpose is served by proceeding to the second [or hardship] prong." George E. Warren Corp. v. EPA, 159 F.3d 616, 622 (1998). In this case the TSCA requires that any petition for review of a rule be filed within 60 days of the promulgation of the rule. 15 U.S.C. s 2618(a)(1)(A). Consequently, having demonstrated that the issue is fit for review, GE need not also show that delaying review would work a hardship. For these reasons, we hold the case ripe for review.

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ine the toxicity of PCBs and has no objection to a remand so that it can consider the results of the assessment. Therefore, we remand ss 761.61(a) and 761.79(b) to give EPA an opportunity to complete its assessment and reconsider the Final Rule in light of its study.

B. Jurisdiction under the TSCA

Before we can reach the merits, we must consider whether the Document is a "rule" subject to our review under s 19(a)(1)(A) of the TSCA, 15 U.S.C. s 2618(a)(1)(A). That section provides:

> Not later than 60 days after the date of the promulgation of a rule under section ... 2605(e) ... of this title, ... any person may file a petition for judicial review of such rule with the United States Court of Appeal for the District of Columbia Circuit.

GE contends that the term "rule" should be read broadly to track the definition in the APA. See 5 U.S.C. s 551(4). The EPA takes the narrower view that "direct appellate review is limited to legislative rules, i.e., rules which were (or should have been) promulgated through notice and comment rule-making." See, e.g., Appalachian Power, 208 F.3d at 1020 & n.11. We need not decide which interpretation of the term "rule" in s 19(a)(1)(A) is correct because we conclude that the Guidance Document is indeed a legislative rule.

GE argues that the Guidance Document is a legislative rule rather than a statement of policy or an interpretive rule because it gives substance to the vague language of 40 C.F.R. s 761.61(c) ("unreasonable risk of injury to health or the environment"), does so in an obligatory fashion, and is treated by the EPA as "controlling in the field." See Community Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987); McLouth Steel Prods. Corp. v. Thomas, 838 F.2d 1317, 1320-22 (D.C. Cir. 1988); Appalachian Power, 208 F.3d at 1021. The EPA argues that under the three-part test applied in Molycorp, Inc. v. EPA, 197 F.3d 543, 545 (D.C. Cir. 1999), the Guidance Document is not a legislative rule. Although it is not entirely clear what in the EPA's view the Document is, the EPA comes closest to characterizing it as a statement of policy; thus:

> [T]he portion of the guidance at issue here is simply an expression of EPA's policy judgment, based on the available scientific data and analysis, that when the "total

> toxicity" analysis is used, the 4.0 (mg/kg/day)-1 toxicity value is appropriate to avoid an unreasonable risk to health or the environment.

With the Agency's argument so understood, the question before us can be framed as whether the Guidance Document is a legislative rule or a statement of policy.

As GE argues, in cases where we have attempted to draw the line between legislative rules and statements of policy, we have considered whether the agency action (1) "impose[s] any rights and obligations" or (2) "genuinely leaves the agency and its decisionmakers free to exercise discretion." Community Nutrition Inst., 818 F.2d at 946; Chamber of Commerce v. Dep't of Labor, 174 F.3d 206, 212 (1999). In McLouth, we recognized that "[i]n practice, there appears some overlap in the Community Nutrition criteria" because "[i]f a statement denies the decisionmaker discretion in the area of its coverage, so that [the agency] will automatically decline to entertain challenges to the statement's position, then the statement is binding, and creates rights or obligations." 838 F.2d at 1320. We emphasized that an agency announcement has "present-day binding effect" if the agency is "simply unready to hear new argument" in proceedings governed by the announcement. Id. at 1321.

The EPA urges the court to consider three factors: "(1) the Agency's own characterization of its action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations; and (3) whether the action has binding effects on private parties or on the agency." Molycorp, Inc., 197 F.3d at 545; see also Florida Power & Light Co. v. EPA, 145 F.3d 1414, 1418 (D.C. Cir. 1998); American Portland Cement Alliance v. EPA, 101 F.3d 772, 776 (D.C. Cir. 1996). As the EPA concedes, however, the third factor is the most important: "[T]he ultimate focus of the inquiry is whether the agency action partakes of the fundamental characteristic of a regulation, i.e., that it has the force of law." Molycorp, Inc., 197 F.3d at 545.

The two tests overlap at step three of the Molycorp formulation--in which the court determines whether the

agency action binds private parties or the agency itself with the "force of law." This common standard has been well-stated as follows:

> If a document expresses a change in substantive law or policy (that is not an interpretation) which the agency intends to make binding, or administers with binding effect, the agency may not rely upon the statutory exemption for policy statements, but must observe the APA's legislative rulemaking procedures.

Robert A. Anthony, Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like--Should Federal Agencies Use Them to Bind the Public?, 41 Duke L.J. 1311, 1355 (1992).

Our cases likewise make clear that an agency pronouncement will be considered binding as a practical matter if it either appears on its face to be binding, Appalachian Power, 208 F.3d at 1023 ("[T]he entire Guidance, from beginning to end ... reads like a ukase. It commands, it requires, it orders, it dictates."), or is applied by the agency in a way that indicates it is binding, McLouth, 838 F.2d at 1321. As Professor Robert A. Anthony cogently comments, the mandatory language of a document alone can be sufficient to render it binding:

> A document will have practical binding effect before it is actually applied if the affected private parties are reasonably led to believe that failure to conform will bring adverse consequences, such as ... denial of an application. If the document is couched in mandatory language, or in terms indicating that it will be regularly applied, a binding intent is strongly evidenced. In some circumstances, if the language of the document is such that private parties can rely on it as a norm or safe harbor by which to shape their actions, it can be binding as a practical matter.

Interpretive Rules, 41 Duke L.J. at 1328-29.

GE argues that the Guidance Document is binding both because it facially requires an applicant for a risk-based

variance to calculate toxicity by one of two methods--either use a total toxicity factor of 4.0 (mg/kg/day)-1 or use a cancer potency factor and account for the specified non-cancer health risks--and because, considering the cost, delay, and uncertainty entailed in the latter course, "[f]or all practical purposes, the Guidance is a rule that directs PCB toxicity to be measured by a 4.0 (mg/kg/day)-1 CPF."

The EPA counters that the Guidance Document lacks the force of law because it does not purport to be binding and because it has not been applied as though it were binding. First, we are told, the Document "allows great flexibility" because it not only "recognizes two broad approaches to risk assessment," but also acknowledges (at 44) that

> some risk assessments may have components that require the use of non-standard reference materials, unique exposure scenarios or assumptions, or require the use of unconventional methods for estimating risks. These risk assessments will need to be addressed on a case-by-case basis.

Second, the EPA says that it has not in practice "applied the guidance document inflexibly, as if it were a rule or regulation." By this, however, the EPA means only that it has received and approved applications based upon the use of the total toxicity factor and upon a separate analysis of cancer and non-cancer risks--and even this limited assertion is disputed by GE. Finally, the Agency contends that the Guidance Document is "an expression of EPA's judgment on values to be used in conducting risk assessments," much like the data in the Agency's Integrated Risk Information System (IRIS), which this court held are not subject to the requirements of notice and comment rulemaking. See Chemical Mfrs. Ass'n v. EPA, 28 F.3d 1259, 1263 (1994).

We think it clear that the Guidance Document does purport to bind applicants for approval of a risk-based cleanup plan under 40 C.F.R. s 761.61(c). Consider the principal directives: "When developing a risk-based cleanup application ... both the cancer and non-cancer endpoints must be addressed...." Guidance Document at 21. If an applicant

chooses not to use the 4.0 total toxicity factor, then it "must, at a minimum account for the risk from non-cancer endpoints for neurotoxicity, reproductive and developmental toxicity, immune system suppression, liver damage, skin irritation, and endocrine disruption for each of the commercial mixtures found at the cleanup site." Id. Although the Guidance Document does, as noted, anticipate and acknowledge that "some risk assessments may have components that require the use of non-standard ... unique ... or unconventional methods for estimating risk," id. at 44, that does not undermine the binding force of the Guidance Document in standard cases. See McLouth, 838 F.2d at 1321 ("such a provision for exceptions ... does not push it much in the direction of a policy statement"). Furthermore, even though the Guidance Document gives applicants the option of calculating risk in either of two ways (assuming both are practical) it still requires them to conform to one or the other, that is, not to submit an application based upon a third way. And if an applicant does choose to calculate cancer and non-cancer risks separately, then it must consider the non-cancer risks specified in the Guidance Document. To the applicant reading the Guidance Document the message is clear: in reviewing applications the Agency will not be open to considering approaches other than those prescribed in the Document.

The Guidance Document also appears to bind the Agency to accept applications using a total toxicity factor of 4.0 (mg/kg/day)-1 to calculate the risk from both cancer and non-cancer endpoints. Guidance Document at 21. The EPA recognized this in its principal brief: "By indicating that [a] total toxicity value [of 4.0 (mg/kg/day)-1] will be accepted without detailed justification, the guidance document offers an applicant an opportunity to reduce the time and expense associated with risk assessment." In its supplemental brief, however, the EPA backs away from this statement, asserting that the "EPA is not 'bound' to approve an application under Section 761.61(c) if the applicant uses a total toxicity factor of 4.0 (mg/kg/day)-1, even assuming that the application falls within the framework of the guidance document." How can this be? According to the Agency, its position with respect to

the total toxicity factor "is a matter of policy" that "can be changed at any time to respond to, inter alia, advances in scientific knowledge." But the Guidance Document itself says nothing of the sort. Clearly the EPA's initial response more accurately describes the Agency's approach in the Document: Stating without qualification that an applicant may use a total toxicity factor of 4.0 (mg/kg/day)-1 strongly implies that use of that value will not be questioned; an applicant reasonably could rely upon that implication.

The EPA argues that the Guidance Document "neither adds to EPA's prior position nor imposes any further obligations on EPA or the regulated community" because the Agency had used the toxicity factor of 4.0 (mg/kg/day)-1 when it "establish[ed] the generic cleanup standards in the 1998 [PCB] regulations." In its supplemental brief, however, the Agency explicitly states that it does not think its use of 4.0 (kg/mg/day)-1 in the 1998 regulations requires it to approve use of that factor in an application under s 761.61(c). Because we conclude that the Guidance Document does bind the Agency to accept use of 4.0 (kg/mg/day)-1, it follows that the Document does indeed impose a "further obligation[ ] on the EPA." In this way the Guidance Document is not like the risk data at issue in Chemical Mfrs., which we held "constrain no one until ... applied in a particular rule." 28 F.3d at 1263.

Furthermore, the EPA does not contend that in practice it has not treated the Guidance Document as binding in the ways described above. The EPA does not claim, for example, that it has accepted any applications that (1) use neither of the two methods of risk assessment approved in the Guidance Document; or (2) calculate risk separately for cancer and non-cancer endpoints, but fail to calculate endpoints for all the non-cancer risks required by the Guidance Document to be addressed. Nor does the EPA contend that it has ever rejected an applicant's use of 4.0 (mg/kg/day)-1. Whether an applicant has successfully used the second method of risk assessment set out in the Guidance Document--as the EPA asserts and GE disputes--is immaterial because, even if both

methods are practically available, the Document nonetheless binds applicants and the Agency in the ways described above.

In sum, the commands of the Guidance Document indicate that it has the force of law. On its face the Guidance Document imposes binding obligations upon applicants to submit applications that conform to the Document and upon the Agency not to question an applicant's use of the 4.0 (mg/kg/day)-1 total toxicity factor. This is sufficient to render it a legislative rule. Furthermore, the Agency's application of the Document does nothing to demonstrate that the Document has any lesser effect in practice. Consequently, we conclude that the Guidance Document is a legislative rule. The Guidance Document is therefore undisputedly a "rule" for purposes of s 19(a)(1)(A) of the TSCA, and the manner of its promulgation is subject to review.

C. The Merits

The EPA concedes that it did not comply with the procedural requirements of the TSCA and of the APA. More specifically, as GE points out, it failed to publish a notice of proposed rulemaking, give interested parties an opportunity to comment, and hold an informal hearing. See 15 U.S.C. s 2605(e)(4); 15 U.S.C. s 2605(c)(2); 5 U.S.C. s 553. Therefore, having held that the case is ripe for review and that the Guidance Document is a "rule" for purposes of the TSCA, it is clear that GE must prevail on the merits. The EPA agrees: "Either the petition must be dismissed for lack of jurisdiction or the PCB Guidance should be vacated." For this reason we need not consider GE's alternative argument on the merits, namely, that the Guidance Document is not supported by substantial evidence.

III. Conclusion

GE's petition for review is granted because the EPA promulgated a legislative rule without following the procedures required by the TSCA and the APA. The Guidance Document is accordingly

Vacated.