United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 17, 2003 Decided June 3, 2003

No. 02-1057

CROPLIFE AMERICA, ET AL.,
PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENT

NATURAL RESOURCES DEFENSE COUNCIL AND
AMERICAN CHEMISTRY COUNCIL,
INTERVENORS

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

Kenneth W. Weinstein argued the cause for petitioners. With him on the brief was *Alexandra A. E. Shapiro*.

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Seth A. Goldberg argued the cause for intervenor American Chemistry Council. With him on the briefs was *Cynthia L. Taub*.

Daniel M. Flores, Attorney, U.S. Environmental Protection Agency, argued the cause for respondent. *Christopher S. Vaden* and *Kent E. Hanson*, Attorneys, entered appearances.

Aaron Colangelo argued the cause for intervenor Natural Resources Defense Council. With him on the brief was *Erik D. Olson*.

Joseph W. Hatchett, *Lee Davis Thames* and *Jerry C. Hill* were on the brief for *amicus curiae* Florida Citrus Mutual, et al., in support of petitioners.

Benjamin S. Sharp was on the brief for *amicus curiae* Washington State Potato Commission in support of petitioners.

Before: GINSBURG, *Chief Judge*, and EDWARDS and GARLAND, *Circuit Judges*.

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

EDWARDS, *Circuit Judge*: This case concerns an Environmental Protection Agency ("EPA" or "the agency") directive banning agency consideration of "third-party" human studies in evaluating the safety of pesticides. In the late 1990s, EPA began reevaluating its practice of relying on data from third-party human studies, and began considering such data on a case-by-case basis only. In October 2001, the agency made this case-by-case practice clear to the regulated community. Then, however, the agency abruptly reversed its position. On December 14, 2001, EPA issued a directive in a Press Release, announcing that, pending review by the National Academy of Sciences ("NAS" or "Academy") of the ethical issues posed by EPA's use of third-party human studies, "the Agency will not consider or rely on any such human studies in its regulatory decision making, whether previously or newly submitted." Environmental Protection Agency, Press Release, *Agency Requests National Academy of Sciences Input on Consideration of Certain Human Toxicity Studies; An-*

nounces Interim Policy, Dec. 14, 2001, Appendix ("App.") 120 ("Press Release").

Petitioners CropLife America, *et al.* – pesticide manufacturers and a trade association that claims that its members will be adversely affected by the announced moratorium – seek review of the directive in the December 14 Press Release. Petitioners contend that the EPA directive is unlawful, because it constitutes a binding regulation that was issued without the notice of proposed rulemaking and period for public comment mandated by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FFDCA"). *See* 21 U.S.C. §§ 346a(e)(1)(C) & (e)(2); *see also* 5 U.S.C. § 553. Petitioners also argue that the policy violates the rule, enunciated in both the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136-136y ("FIFRA"), and FFDCA, requiring EPA to consider all relevant reliable data. *See* 7 U.S.C. § 136a-1(g)(1); 21 U.S.C. § 346a(b)(2)(D). Finally, petitioners assert that the policy is arbitrary and capricious in violation of the Administrative Procedure Act, 5 U.S.C. §§ 701-706. *See* 5 U.S.C. § 706(2)(A) ("The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. . . .").

We hold that EPA's directive constitutes a binding regulation issued without notice and the opportunity for comment. We therefore grant the petition for review and vacate the new rule. As a consequence, the agency's previous practice of considering third-party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide, is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated regulation.

I. Background

EPA oversees a comprehensive scheme of pesticide regulation under FIFRA and FFDCA. While FIFRA governs pesticide registration, FFDCA regulates pesticide residues in the food supply. Originally enacted in 1947, FIFRA estab-

lishes a registration system allowing EPA to prescribe the conditions under which a pesticide may be sold or distributed. In determining whether to register a pesticide under FIFRA, EPA considers whether the pesticide would cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C). To determine whether the pesticide would cause such unreasonable environmental effects, the agency determines whether it would produce an "unreasonable risk to man" or any "human dietary risk." 7 U.S.C. § 136(bb). Under FFDCA, EPA regulates the amount of pesticide that may remain on food products, establishing "tolerance levels" for pesticide residues on raw and processed food products. 21 U.S.C. § 346a(b)(1).

The FFDCA provision dealing with the method of setting tolerances for pesticides was substantially revised by the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 ("FQPA"). *See* 21 U.S.C. § 346a (governing tolerances for pesticide chemical residues); *see also* Andrew J. Miller, Note, *The Food Quality Protection Act of 1996: Science and Law at a Crossroads*, 7 DUKE ENVTL. L. & POL'Y F. 393, 403 (1997) ("The FQPA rewrites most of section 408 of the FFDCA."). The revised provision defines pesticide tolerances as "safe" when there is "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii). In determining whether pesticide tolerances are safe, EPA may consider the validity of the available data from studies, anticipated and actual residue levels of the pesticide in or on foods, the percent of food actually treated with the pesticide, and international standards. *See* 21 U.S.C. § 346a(b)(2)(D)-(F), (b)(4).

In 1988, Congress amended FIFRA to require that every pesticide registered before 1984 be reregistered under present-day standards. Pub. L. No. 100-532, 102 Stat. 2654 (codified as amended in scattered sections of 7 U.S.C.). In 1996, Congress also set deadlines for EPA to review all existing tolerances against the new standard established by the FQPA. 21 U.S.C. § 346a(q). As a result, the agency is

currently in the process of reexamining thousands of regulated pesticides. This process involves years of preliminary action and evaluation under both FIFRA and FFDCA, culminating in public pronouncements of the agency's position on the safety of a given pesticide.

For decades, EPA accepted and relied upon third-party human data in evaluating pesticide safety. However, the agency's position shifted in 1998. On July 27, 1998, EPA stated publicly that it would ask an internal review board to reevaluate the agency's use of third-party human studies. EPA Statement, July 27, 1998, App. 11. EPA's statement also indicated that "[n]o human test data has been used by EPA for any final decisions about acceptable levels of pesticide use under the [1996 FQPA]." *Id.* An October 1998 internal EPA memorandum amplified this statement, indicating that EPA's policy was to consider only third-party human data that meets "the highest ethical standards." Memorandum from Peter D. Robertson, Acting Deputy Administrator, EPA, to EPA Assistant Administrators 3 (Oct. 9, 1998), App. 14. Although the July 1998 statement signaled the beginning of EPA's reconsideration of the role of human testing, the agency's Office of Pesticide Programs continued to review human test data and to discuss the results of such reviews in the public record of regulatory decisions. *See* OFFICE OF PESTICIDE PROGRAMS, ENVTL. PROT. AGENCY, ROLE OF HUMAN STUDIES IN THE OFFICE OF PESTICIDE PROGRAMS 3 (2001), App. 118.

As part of its policy development process, EPA appointed a Joint Subcommittee of its Science Advisory Board and FIFRA Scientific Advisory Panel ("the Joint Subcommittee") to evaluate the circumstances under which third-party human data should be considered. In September 2000, the Joint Subcommittee issued a report addressing the ethical and scientific acceptability of utilizing such data. The report "envision[ed] particular circumstances under which such dosing of humans could be scientifically and ethically acceptable," but found such circumstances "very difficult" to define. ENVTL. PROT. AGENCY, COMMENTS ON THE USE OF DATA FROM THE TESTING OF HUMAN SUBJECTS: A REPORT BY THE SCIENCE ADVISORY

BOARD AND THE FIFRA SCIENTIFIC ADVISORY PANEL 2 (2000), App. 34. Sixteen panel members recommended that the agency continue to consider human studies under strict standards, while two members advocated a blanket ban on such tests. *Id.* at 1-4, App. 33-36.

Thereafter, in October 2001, EPA made clear that it would consider data from third-party human studies on a case-by-case basis. *See* John Heilprin, *EPA Using Human Testing Data from Manufacturers in Evaluating Pesticide Regulations, Exposure Levels*, ASSOCIATED PRESS, Nov. 27, 2001, LEXIS, News Library, News Group File; Shogren, *supra*; Shankar Vedantam, *EPA Used Data from Human Pesticide Tests*, WASH. POST, Nov. 29, 2001, at A6. In several pesticide regulatory decisions issued around the time of the announcement, EPA in fact considered available human data. *See, e.g., Interim Reregistration Eligibility Decision for Azinphos-Methyl*, Case No. 0235, at 10-11 (EPA Oct. 30, 2001), App. 88-89; *Interim Reregistration Eligibility Decision for Phosmet*, Case No. 0242, at 8 (EPA Oct. 30, 2001), App. 92; *Interim Reregistration Eligibility Decision for Chlorpyrifos*, Case No. 0100, at 16 (EPA Sept. 28, 2001), App. 85. However, the agency's decision to resume consideration of such data provoked criticism, primarily from environmental groups. *See, e.g.*, Katharine Q. Seelye, *E.P.A. Reconsiders Human Tests of Pesticides*, N.Y. TIMES, Dec. 15, 2001, at A14 (quoting Richard Wiles, senior vice president of the Environmental Working Group, as saying that "[t]he administration would be in an awkward position if it was against stem-cell research but for dosing people up directly with pesticides").

On December 14, 2001, EPA announced a broad moratorium on the use of third-party human test data. EPA publicly released a letter to the NAS in which the agency sought the Academy's recommendations regarding the ethical and scientific acceptability of third-party human pesticide tests. *See* Letter from Stephen L. Johnson, Assistant Administrator, EPA, to Dr. Bruce Alberts, President, National Academy of Scientists 1-3 (Dec. 14, 2001), App. 121-23. In a Press Release accompanying the letter's release, the agency issued the following directive covering third-party human studies:

> During the Academy's consideration of the issues and until a policy is in place, the Agency will not consider or rely on any such human studies in its regulatory decision making, whether previously or newly submitted. Should EPA be legally required to consider or rely on any such human study during this interim period, the Agency will assemble a Science Advisory Board subpanel to review and comment on scientific appropriateness and ethical acceptability of the study in question, and the Agency will provide an opportunity for public involvement.

Press Release, App. 120-21.

Petitioners now challenge this directive. The American Chemistry Council intervenes on petitioners' behalf, while the Natural Resources Defense Council ("NRDC") intervenes on EPA's behalf.

II. Analysis

The principal issue in this case is whether the EPA directive that is included in the December 14 Press Release constitutes a binding regulation. In defending against the petition for review, most of EPA's arguments are predicated on the assumption that the directive in the Press Release is not a binding regulation, primarily because of the language allowing EPA to consider third-party human studies if the agency is "legally required to consider or rely on any such human study." EPA thus argues that the matter in dispute is not subject to judicial review, that petitioners lack standing, and that the challenge is not ripe for review. EPA also questions the timeliness of the petition. We have little trouble determining that the directive announced in the December 14 Press Release is indeed a binding regulation. This being the case, the agency's other arguments rapidly fall by the wayside.

The disputed directive constitutes a binding regulation that is directly aimed at and enforceable against petitioners. It provides that "the Agency will not consider or rely on any [third-party] human studies in its regulatory decision mak-

ing." This clear and unequivocal language, which reflects an obvious change in established agency practice, creates a "'binding norm'" that is "'finally determinative of the issues or rights to which it is addressed.'" *Chamber of Commerce v. United States Dep't of Labor*, 174 F.3d 206, 212 (D.C. Cir. 1999) (quoting *Pacific Gas & Elec. Co. v. FPC*, 506 F.2d 33, 38 (D.C. Cir. 1974)); *see also Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002) ("[A]n agency pronouncement will be considered binding as a practical matter if it either appears on its face to be binding, or is applied by the agency in a way that indicates it is binding.") (citations omitted). EPA's stated rule is binding on petitioners, who are now barred from relying on third-party human studies (even in cases where such studies formerly were approved), and is binding on the agency because EPA has made it clear that it simply "will not consider" human studies.

The fact that the directive also notes that third-party human test data can be considered if the agency is "legally required to consider or rely on such human study" does not at all alter our conclusion. This language merely contemplates the possibility of a successful court challenge to the disputed rule; it suggests that if an Article III court were to require the agency to consider a third-party human study, the agency will then "assemble a Science Advisory Board subpanel to review and comment on scientific appropriateness and ethical acceptability of the study in question."

In its argument to this court, EPA claims that the "legally required" language could be read to mean that Administrative Law Judges are authorized to rule on particular third-party human studies after EPA completes its review of a pesticide without the agency considering that data. The directive says no such thing. Indeed, the reality of agency operations makes it clear that ALJs *cannot* independently rule on the legality of third-party human studies, because they may not ignore the Administrator's unequivocal statement prohibiting the agency from considering such studies. *See, e.g., Iran Air v. Kugelman*, 996 F.2d 1253, 1260 (D.C. Cir. 1993) ("It is commonly recognized that ALJs are entirely subject to the agency on matters of law.") (internal quotations omitted);

Mullen v. Bowen, 800 F.2d 535, 540 n.5 (6th Cir. 1986); Antonin Scalia, *The ALJ Fiasco – A Reprise*, 47 U. CHI. L. REV. 57, 62 (1979); *see also Ass'n of Admin. Law Judges, Inc. v. Heckler*, 594 F. Supp. 1132, 1141 (D.D.C. 1984) ("Although an ALJ may dispute the validity of agency policy, the agency may impose its policy through the administrative appeals process.").

The agency attempts to bolster its argument that the directive is non-binding by pointing to *Reliable Automatic Sprinkler Co. v. Consumer Product Safety Commission*, 324 F.3d 726 (D.C. Cir. 2003) ("*Reliable*"). This case is inapposite. In *Reliable*, we determined that the District Court lacked jurisdiction to review the Consumer Product Safety Commission's ("CPSC") process absent final agency action. *Id.* at 729, 732-35; *see also* 5 U.S.C. § 704 (limiting the District Court's review of administrative agencies to cases that challenge "final agency action"). CPSC officials had sent the Reliable Automatic Sprinkler Company a letter stating that the agency intended "to make the preliminary determination that [Reliable's] sprinklers present a substantial product safety hazard." *Reliable*, 324 F.3d at 730 (internal quotations omitted). However, before making that determination, CPSC officials requested that Reliable undertake "voluntary corrective action." *Id.* (internal quotations omitted). Reliable's suit against CPSC sought a declaratory judgment that its sprinkler heads should not be considered consumer products under the Consumer Product Safety Act, 15 U.S.C. § 2051 *et seq.* *See* 15 U.S.C. § 2052(a)(1) (defining "consumer products"). The court held that there was no final agency action in *Reliable*, because "[n]o legal consequences flow from the agency's conduct to date, for there has been no order compelling Reliable to do anything." *Reliable*, 324 F.3d at 732. If CPSC wished to make a formal determination that Reliable's sprinklers presented a substantial product safety hazard, it was required by the Consumer Product Safety Act to afford Reliable "an opportunity for a hearing in accordance with the formal, on-the-record adjudication requirements of the Administrative Procedure Act ('APA'), 5 U.S.C. § 554." *Id.* at 729; *see also* 15 U.S.C. § 2064(c), (d), (f). In that

hearing, Reliable would have the chance to present the very arguments that it attempted to advance before this court. In this case, by contrast, EPA has enacted a firm rule with legal consequences that are binding on both petitioners and the agency, and petitioners will be afforded no additional opportunity to make the arguments to the agency that they now present in this petition.

After oral argument in this case, in an attempt to advance the argument that the directive does not bar consideration of third-party human studies, NRDC submitted a copy of an EPA decision, *Interim Reregistration Eligibility Decision for Atrazine*, Case No. 0062 (EPA Jan. 31, 2003) ("*Atrazine IRED*"), recently published for public comment at 68 Fed. Reg. 9652 (Feb. 28, 2003). NRDC asserts that EPA relied on an industry human study in *Atrazine IRED* to measure the extent to which the pesticide is absorbed into human skin, thus showing that the disputed directive does not foreclose consideration of such data. NRDC's argument is unavailing, for the decision sheds no light whatsoever on the disputed directive. *Atrazine IRED* does not purport to enunciate or apply any policy at all. Indeed, EPA does not suggest otherwise.

EPA and NRDC also argue that the directive in the Press Release is nothing more than a "policy statement," and thus is not subject to judicial review. *See* 21 U.S.C. § 346a(h)(1) (limiting the court's jurisdiction to cases of "actual controversy as to the validity of any *regulation* issued under subsection (e)(1)(C)") (emphasis added). We reject this argument. As a general matter, the case law reflects two related formulations for determining whether a challenged action constitutes a regulation or merely a statement of policy. One line of analysis focuses on the effects of the agency action. *See, Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (stating that the court should consider whether the agency action (1) "impose[s] any rights and obligations," or (2) "genuinely leaves the agency and its decisionmakers free to exercise discretion") (internal quotations omitted); *See also, e.g., Troy Corp. v. Browner*, 120 F.3d 277, 287 (D.C. Cir. 1997); *Am. Bus. Ass'n v. United States*, 627 F.2d 525, 529

(D.C. Cir. 1980). The second line of analysis focuses on the agency's expressed intentions. *See Molycorp., Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999) (stating that the court should consider "(1) the Agency's own characterization of the 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"); *see also, e.g., Am. Portland Cement Alliance v. EPA*, 101 F.3d 772, 776 (D.C. Cir. 1996). However, as we recently noted in *General Electric v. EPA*, 290 F.3d 377, these two lines of analysis 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.'" *Id.* at 382. *General Electric* and other cases also make it clear that the agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the "force of law," but the record indicates otherwise. *See Gen. Elec.*, 290 F.3d at 383-85; *see also, e.g., Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 95-96 (D.C. Cir. 2002).

In the instant case, there is little doubt that the directive in the December 14 Press Release "binds private parties [and] the agency itself with the 'force of law,'" *Gen. Elec.*, 290 F.3d at 382, and thus constitutes a regulation rather than a policy statement. The directive clearly establishes a substantive rule declaring that third-party human studies are now deemed immaterial in EPA regulatory decisionmaking under FFDCA and FIFRA.

The agency's arguments that petitioners' claims should be dismissed for want of standing and ripeness are also without merit. EPA asserts that petitioners lack standing because the agency may consider third-party human studies after a determination that it is legally required to do so, and because setting aside the directive would leave in place a practice that may still result in the rejection of petitioners' third-party human studies. *See, e.g., Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (noting that injury-in-fact, causation, and redressability are requirements for Article III standing); *Util. Air Regulatory Group v. EPA*, 320 F.3d 272, 277 (D.C.

Cir. 2003) (same). EPA's argument is meritless. The disputed directive concretely injures petitioners, because it unambiguously precludes the agency's consideration of all third-party human studies, *i.e.*, studies that petitioners previously have been permitted to use to verify the safety of their products. There is no doubt that the injury is caused by the new rule, nor is there any doubt that this injury can be redressed if the court vacates the new rule and reinstates the agency's previous practice of considering third-party human studies on a case-by-case basis. Petitioners do not seek to require the agency to consider any particular human study. Instead, they simply ask the court to enjoin the agency's blanket refusal to consider any third-party human studies. Petitioners' standing to pursue this lawsuit is clear.

As to ripeness, EPA argues that petitioners' claim is unripe "because an ALJ, the Administrator or the EAB may allow a third-party study into evidence in a hearing process, or the Administrator may make a 'legal requirement' determination in a rulemaking." Br. of Respondent at 27. This argument is plainly wrong, because the EPA directive states unequivocally that the agency will not consider *any* third-party human studies unless a court orders it to do so. Thus, because it presents a purely legal question that does not "depend upon consideration of . . . particularized facts," *Mountain States Tel. & Tel. Co. v. FCC*, 939 F.2d 1035, 1041 (D.C. Cir. 1991), petitioners' claim is ripe for review.

Finally, EPA argues that petitioners' claim is time-barred, "because EPA has made similar statements in the past." Br. of Respondent at 29. In particular, EPA contends that, "[i]f there were a challenge to bring . . . it should have been brought within 60 days" of one of the earlier EPA statements on human test subjects. *Id.* at 30; *see also* 21 U.S.C. § 346a(h)(1). This argument is meritless. The directive in the Press Release differs markedly from the agency's past statements, because the new rule clearly represents the first time that the agency has adopted an unequivocal, wholesale ban on the consideration of third-party human studies. Moreover, the agency indisputably opened the issue anew in 2001 by first announcing that it would consider third-party

human studies on a case-by-case basis and then stating that it would not consider any such studies. *See Ass'n of Am. R.R. v. ICC*, 846 F.2d 1465, 1473 (D.C. Cir. 1988) ("[I]f the agency has opened the issue up anew, even though not explicitly, its renewed adherence is substantively reviewable.").

Because the new rule effects a dramatic change in the agency's established regulatory regime, EPA was required to follow notice and comment procedures under 21 U.S.C. § 346a(e)(1)(C) & (e)(2). This was not done. Therefore, we vacate EPA's rule for failure to comply with FFDCA's notice and comment requirements. *See, e.g., Gen. Elec.*, 290 F.3d at 385; *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000).

III. Conclusion

For the reasons enumerated above, we vacate the directive articulated in EPA's December 14, 2001 Press Release for a failure to engage in the requisite notice and comment rule-making. The consequence is that the agency's previous practice of considering third-party human studies on a case-by-case basis, applying statutory requirements, the Common Rule, and high ethical standards as a guide, is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated regulation.