schedule for these should be coordinated to coincide with a scheduled FDA audit or FDA inspection.

7. Access to Quality Assurance Reports.
EPA is considering subjecting a company's quality assurance records to routine inspection. There are several reasons why this idea would be a mistake. First, it is self-defeating. The purpose of a quality control system is to encourage quick and candid identification and correction of process problems. Making such records public discourages frank, fast identification and correction. Second, it is impracticable. Faced with such a requirement, quality assurance correspondence would undoubtedly be written "for the record" and internal communications would increasingly become oral. Thus, routine inspection of such records could become a dry exercise. Third, FDA recognized the desirability of permitting laboratories to maintain the privacy of Quality Assurance Unit reports. FDA distinguishes between its right to inspect a company's manufacturing quality control records, which are an integral part of the manufacturing process, and management audits of the manufacturing function as part of a general overview of management practice. The Quality Assurance Unit is considered an "Inspector General" function and FDA has decided as a matter of policy that the objectives of a Quality Assurance Unit would be best served by exempting such reports from FDA inspector access.

The FIFRA GLP proposals are based on the TSCA GLP proposals discussed above. However, as is common with other proposals since the original FDA GLP regulations, there has been a continual refinement and less flexibility. The FIFRA GLP proposals enhance the requirements for the chemical analysis of mixtures, record and sample retention, availability of records, definition of raw data, use of protective clothing, safeguarding the integrity of data, and archival records.

EDF v. Costle: EPA's New Case for Pesticide Regulation

Lawrence S. Ebner
McKenna, Conner & Cuneo

When pesticide manufacturers or users believe that EPA has gone too far in proposing to prohibit or restrict usage of a pest control chemical, they can take their case to an administrative law judge, and if necessary, to a federal court of appeals. But can environmental interest groups or anyone else do the same and argue that EPA has not gone far enough? According to a recent panel of federal judges, the answer is "no."

This landmark ruling was announced on July 17, 1980 by the United States Court of Appeals for the District of Columbia Circuit in *Environmental Defense Fund v. Costle* (No. 79-1971).[1] The decision reaffirms EPA's discretion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to determine the maximum degree to which use of a registered pesticide should be restricted to prevent "unreasonable adverse effects on the environment" (FIFRA § 6(b), 7 USC § 136d(b)). Pesticide producers and users can be assured that once the agency reaches such a determination, a public hearing cannot be convened under Section 6(b)(1) for the purpose of persuading an administrative law judge that the agency's action ought to be more restrictive. Advocates of cancellation or other stringent action, however, can pursue the informal public comment procedures established by EPA to facilitate the agency's determination of what regulatory action to take, and can recommend that before reaching a decision, the Administrator hold a hearing under Section 6(b)(2) to hear testimony from all interested parties.

BACKGROUND AND RULING

EDF v. Costle arose out of EPA's three-year rebuttable presumption against registration (RPAR) review of a widely-used miticide known as Chlorobenzilate. The purpose of the RPAR review was to assemble and study, with public input from interested parties, information on the risks and benefits of Chlorobenzilate and its various uses. The agency would then be in a position to initiate, on a use-by-use basis, whatever regulatory action it deemed appropriate.[2]

Following completion of the RPAR review, the Assistant Administrator for Pesticides and Toxic Substances issued a notice cancelling unconditionally all registered uses of

Chlorobenzilate, except for its uses on citrus crops. The latter were to be cancelled only "conditionally," that is, the citrus uses would be retained upon acceptance by Chlorobenzilate registrants of certain new usage safeguards (for example, all applicators must wear protective clothing and must either be certified or work under the supervision of a certified applicator).

Ciba-Geigy Corporation, the principal Chlorobenzilate registrant, decided to waive its statutory right under Section 6(b) of FIFRA to object to and request a public hearing on the regulatory actions announced by EPA. The company thereby indicated its readiness to accept the cancellation of the noncitrus uses and the new restrictions for future usage of Chlorobenzilate on citrus crops. Timely objections and a request for a hearing were filed only by the Environmental Defense Fund (EDF), which advocated unconditional cancellation of *all* Chlorobenzilate uses, including the citrus uses. Objections and requests for a hearing filed by several user groups, which contended that EPA had gone too far in imposing the new limitations on the citrus uses, were rejected as untimely.

Following issuance of a notice to show cause and consideration of legal briefs, EPA's Chief Administrative Law Judge rendered an accelerated decision. He dismissed EDF's request for a hearing on the ground that EDF was not "adversely affected" by the cancellation notice, and hence, not entitled to request the trial-type administrative hearing afforded by Section 6(b). The Administrator affirmed, and EDF sought review in the Court of Appeals pursuant to FIFRA § 16(b) (7 USC § 136n(b)). Ciba-Geigy (joined by the National Agricultural Chemicals Association (NACA) as amicus curiae) intervened in support of EPA's position that EDF was not entitled to a public hearing on the question of whether the agency's regulatory action on Chlorobenzilate's citrus uses was adequate.

The court was confronted with the issue of whether a group seeking to challenge the adequacy of a cancellation action is entitled to demand an administrative trial under Section 6(b) of FIFRA. Ten years earlier, the court had held in connection with the DDT proceedings that EDF has standing to ask a federal court to rule on the narrow issue of whether the agency has adhered to statutory standards in refusing to cancel a pesticide.[3] EDF had not suggested until now, however, that it is entitled to an administrative trial on an agency determination to withhold more stringent regulatory action.

In the present case, the attorneys for EPA and EDF directed their arguments to the question of whether EDF was "adversely affected" by the Chlorobenzilate cancellation notice since, under Section 6(b), a request for a hearing may be made "by a person adversely affected by the notice." On behalf of Ciba-Geigy and NACA, the author argued a more fundamental point: the statute does not establish for EDF or anyone else (whether "adversely affected" or not) any procedure for initiating a public hearing on the Administrator's decision to *retain* a pesticide registration. EPA's "conditional cancellation" of the Chlorobenzilate citrus uses was in reality such a decision to retain registrations (albeit with additional restrictions), and not to cancel.

The court concurred fully in the approach advocated on behalf of Ciba-Geigy and NACA:

> . . . we do not reach the issue of whether EDF is adversely affected by the notice, because we conclude that no hearing right is available to challenge only the retention or permissive portion of a cancellation notice.
>
> That is, *does Section 6(b) compel the EPA to hold an administrative hearing when the only proffered objection concerns the retention portion of a notice of cancellation?* We hold that it does not.

The court held that "[t]o the extent EDF challenges the *retention* of registration as restricted, it is not entitled to an administrative hearing;" the structure and language of FIFRA § 6(b) "speaks only in terms of cancellation decisions." The court noted the pattern within FIFRA which "seems to be that decisions regulating more strictly may be challenged in administrative hearings, those regulating less strictly may not."

As to parties such as EDF seeking "more stringent regulation," that is, those "seeking review of the permissive aspect of the agency decision (i.e., the retention of certain erstwhile qualified uses)," the court observed that they "may challenge these notice provisions in district court" pursuant to Section 16(a) of FIFRA (7 USC § 136n(a)). Unlike the de novo review at an administrative trial held under Section 6, the scope of judicial review under Section 16(a) of "final agency actions" (such as a "conditional cancellation" action to retain a pesticide registration) is limited to the question of whether the agency has acted arbitrarily, capriciously, or otherwise unlawfully.[4]

THE JURISDICTIONAL ISSUE

Quite apart from the issue of the availability of a public hearing on the Chlorobenzilate cancellation notice, Ciba-Geigy and NACA asserted as a threshold matter that the

Court of Appeals was without jurisdiction to entertain the case and that it should have been brought instead in federal district court. Since 1972, Section 16 of FIFRA has limited the original review jurisdiction of the courts of appeals to "any order issued by the Administrator following a public hearing;" all "other final agency actions not committed to agency discretion by law are judicially reviewable in the district courts." The author argued that the denial of EDF's (and the citrus user groups') requests for a hearing was not the sort of matured "order" following an evidentiary and at least partly auditory "public hearing" which Congress had in mind in limiting direct review by the appellate courts.

The Court of Appeals rejected this jurisdictional argument and agreed with the other parties that "the record before [the court]. . . is wholly adequate for judicial review." In so holding, the court reasoned that a factual record, indisputably absent in this appeal, is not necessary where the issue under review is entirely one of law. The court stated that the intent underlying Section 16(b) is to ensure "that review be based on an administrative decision with an adequate record." Ironically, the "public hearing" recognized by the court for purposes of establishing jurisdiction was the summary paper process by which the agency denied EDF's and the user groups' requests for a public hearing on the Chlorobenzilate cancellation actions.

□

The court's interpretation of Section 6(b) makes it clear that FIFRA does not afford the right to demand an adjudicatory hearing to parties who contend that a regulatory action on a pesticide's uses is inadequate. On the other hand, adversely affected parties seeking to challenge the agency action as too restrictive remain entitled to the trial-type hearing afforded by Section 6(b)(1).

The ruling has important meaning for EPA, for pesticide registrants and users, and for environmental interest groups. First, EPA can proceed confidently in determining what it considers to be the appropriate maximum degree of restriction on a pesticide. As suggested by the recently proposed RPAR and Hearing Reform Rules,[5] the agency plans to increase the use of RPARs to marshall and evaluate available data on "problem" pesticides and to formulate regulatory actions on a use-by-use basis. These can range from unconditional cancellation, through retention with additional restrictions, to retention as is. The adequacy of the regulatory action thus initiated is not susceptible to challenge in an adjudicatory proceeding under Section 6(b)(1). Good-faith consideration by the agency of the information developed during the course of an RPAR should help insulate the agency from a charge that a resultant action is arbitrary or capricious.

Second, pesticide registrants and user groups can continue to submit information during an RPAR review in support of regulatory options intended to reduce risks to acceptable levels warranting continued registration rather than cancellation. Once implemented by the agency, such options are not subject to adjudicatory review on the ground that they are insufficient to prevent unreasonable adverse effects on the environment. Even if an environmental interest group could overcome the considerable burden of convincing a federal court that the agency determination represents an abuse of discretion, the court would have to be persuaded to order the agency to issue a more stringent cancellation notice.

Third, environmental interest groups, which to date have participated only nominally in most RPAR reviews, probably should consider channeling their views more actively into the RPAR process, and directing their efforts toward persuading EPA to take the regulatory actions which they advocate (as noted, such groups can also recommend that a Section 6(b)(2) hearing be held). When public hearings are held under Section 6(b)(1) on the necessity of a cancellation action, environmental interest groups, as in the past, will be able to participate as intervenors in support of the agency's cancellation notice. Thus, contrary to EDF's protestations, the court's decision does not deprive environmental interest groups of their opportunity to be heard.

The court's jurisdictional ruling may also have some practical consequences. While the ruling can be limited to the conditions of this case (since the court found there was an "adequate record" on the legal issues involved), it remains unclear whether other types of agency determinations, for which an informal administrative record has been generated, would be regarded as adequate for direct appellate review.

At this writing, EDF plans to file a petition for certiorari. The percentage of such petitions which are granted is quite low. Thus, barring an unexpected reversal by the Supreme Court, EPA has won a major victory under FIFRA.

---

[1]Slip opinion is reprinted at 10 *Environmental Law Reporter* 20585.

[2]See Ebner, "Rebuttable Presumption Against Registration: How EPA Has Improved Pesticide Review," *Environmental Regulation Analyst*, Vol. 1, No. 4 (March 1980).

[3]See *EDF v. Hardin*, 428 F.2d 1093 (1970); *EDF v. Ruckelshaus*, 439 F.2d 584 (1971).

[4]See generally EDF V. Ruckelshaus, supra.

[5]45 *Fed. Reg.* 52628 (August 7, 1980)