Rebuttable Presumption Against Registration: How EPA Has Improved Pesticide Review

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The Environmental Protection Agency's (EPA's) pesticide program finally may have come of age with the advent of the rebuttable presumption against registration (RPAR) process for review of registered pesticides.

Just a few years ago, Agency reviews of registered pesticides typically began with publication of cancellation notices. A suspect chemical literally was placed on trial before an administrative law judge, and sharp battle lines were drawn both for and against outright cancellation. Teams of lawyers for EPA and for public interest groups, such as the Environmental Defense Fund, conducted the prosecution, while lawyers for registrants, user groups, and the Department of Agriculture presented the defense. Testimony in support of or in opposition to cancellation was elicited by direct- and cross-examination of subpoenaed witnesses. Before a decision or settlement could be reached, months of hearings would be expended, and roomfuls of transcripts generated. To many, this adversarial process was cumbersome and expensive, if not unresponsive to the statutory mandate of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). FIFRA requires cancellation of those pesticides generally causing "unreasonable adverse effects on the environment." FIFRA §6(b).

The inordinately long DDT, Aldrin/Dieldrin, and Heptachlor/Chlordane cancellation hearings of the early and mid-1970s, and the prospect of many more seemingly interminable proceedings, may have been enough to convince the Agency to develop a better pesticide review system, but congressional pressure was another compelling consideration. EPA failed to fulfill the 1972 legislative directive to review all registered pesticides and to reregister them as warranted within the required five-year period. (Now, EPA must complete review and reregistration "in the most expeditious manner practicable.") FIFRA §3(g). The result was the creation of the rebuttable presumption against registration process, which substantially removed pesticide review from the courtroom.

RPAR review has enabled Agency regulators and scientists to work together with registrants and other interested parties in assessing the risks and benefits of large numbers of pesticides, and in seaching for ways to retain valuable pesticides by enhancing their safe usage. The RPAR process thus has effected the "more finely tuned control of pesticides" envisioned by Congress when it comprehensively overhauled FIFRA in 1972. S. REP. NO 92-838, 92d Cong., 2d Sess. 5 (1972).

THE RPAR PROCESS

RPAR is EPA's internal review mechanism for determining whether a pesticide poses a "substantial question of safety"—the test identified by the United States Court of Appeals for the District of Columbia in *Environmental Defense Fund v. Ruckelshaus*, 439 F.2d 584 (1971), for determining whether a formal cancellation action is required under section 6(b) of FIFRA.

A "rebuttable presumption" is a legal concept. An RPAR, therefore, is a scientific review within a legal framework. An RPAR is somewhat unique, however, because (1) it does not arise in an adjudicatory context, (2) there are specific regulatory criteria giving rise to the presumption, and (3) there are specific provisions describing how the presumption can be rebutted.

EPA created the RPAR process by regulation in 1975 (40 Fed. Reg. 28, 242). The RPAR regulations provide that a presumption against registration arises whenever the toxicological characteristics of a pesticide meet or exceed any of the acute, chronic, or emergency treatment risk

criteria established by the Agency as triggers for issuance of a cancellation notice. 40 C.F.R. §162.11(a). The presumption is "rebuttable"—at least in theory—because registrants and other interested parties are afforded an opportunity, through written submission of scientific data and other relevant information, to convince the Agency that the presumption is in error and that a pesticide should not be cancelled.

How An RPAR Arises

Consider this hypothetical product involved in a not-so-hypothetical situation. ZAP is a broad-spectrum insecticide, which has been registered for use since 1951. It primarily is applied by air to alfalfa fields as a seed dressing for rutabagas, and around the garden for control of long-tailed mealybugs. There also are many minor registered uses.

The staff of EPA's Special Pesticide Review Division is concerned about ZAP. A recent chronic feeding study sponsored by the Agency demonstrated that ZAP induces teratogenic effects in pregnant hamsters at 10.0 mg/kg/day or higher. Furthermore, a woman, who resides near alfalfa fields treated with ZAP, wrote to the Agency to complain that she gave birth to a child with a cleft palate. To make matters worse, the Agency's Pesticide Incident Monitoring System reported that a biology student has discovered a dead eagle in a patch of rutabagas treated with ZAP, and that a dog died shortly after rolling around in some ZAP accidentally spilled by his master on the garage floor. The National Audubon Society and the Environmental Defense Fund wrote letters to the Administrator demanding that all uses of ZAP be suspended immediately, and then cancelled.

Before the advent of the RPAR process, the Agency might well have proceeded directly to issuance of a cancellation notice on ZAP. The regulatory fate of ZAP then largely would have been resolved in a courtroom before an administrative law judge with little, if any, attention being directed toward the possibility of obviating the need for cancellation by development of additional usage restrictions and safety precautions.

Now that the RPAR process has been established, however, the Agency probably would initiate an RPAR review of ZAP. On the basis of the facts described above, it still would be far from certain that all or any of the uses of ZAP ultimately would be cancelled by the Agency.

Regulatory Criteria

Before the Notice of RPAR is issued, the Agency staff assembles and reviews whatever literature and data may be necessary to assess the toxicological characteristics of the pesticide in terms of the acute and chronic risk criteria described in the RPAR regulations. In the case of ZAP, the applicable risk criteria would include those for teratogenicity, fatality to members of an endangered species, and acute hazard to domestic animals. Other risk criteria described in the RPAR regulations are: acute hazard to humans through dermal or inhalation exposure, hazard to wildlife, oncogenicity, mutagenicity, other chronic effects (such as delayed neurotoxicity), and lack of emergency treatments. 40 C.F.R. §162.11(a)(3).

RPAR Procedure

If the Agency determines that the pesticide under review meets or exceeds any of the risk criteria, the Assistant Administrator for Toxic Substances would publish a Notice of RPAR in the *Federal Register* along with a staff position document. The Notice and Position Document advises that a rebuttable presumption against registration has arisen and presents the evidence relied upon by the Agency as to each risk criterion.

Registrants and other interested parties are afforded sixty days (and for good cause shown, up to an additional forty-five days) within which to submit written presentations of data and other relevant scientific information, either in rebuttal or in support of the RPAR. The RPAR regulations indicate that the presumption against registration can be rebutted by demonstrating that usage of the pesticide will not result in any "significant [acute or chronic] adverse effects." 40 C.F.R. §162.11(a)(4). The Agency also invites submission of "evidence as to whether the economic, social and environmental benefits of the use of the pesticide subject to the presumption outweigh the risk of use." 40 C.F.R. §162.11(a)(5)(iii). Such benefits information is considered by the Agency in connection with the risk/benefit analysis that follows an unsuccessful rebuttal.

If a registrant can rebut successfully each of the criterion cited by the Agency, commencement of a formal cancellation proceeding is averted. If, in the opinion of the Agency, the presumption remains unrebutted, however, cancellation of the pesticide will follow, unless proponents of continued registration can convince the Agency to retain particular registered uses on the ground that the benefits of usage outweigh the risks. In this regard, the Agency would consider, in lieu of outright cancellation, imposition of possible risk reduction measures, such as limiting usage to certified professional applicators, or adding new safety precautions or procedures to the label. The Secretary of Agriculture and the FIFRA Scientific Advisory Panel (as well as those opposed to and supporting continued registration) would have an opportunity to file their views with the Agency. FIFRA §§6(b) and 25(d).

The regulatory actions to be taken as a result of the RPAR review are announced first in a Notice of Preliminary Determination and Position Document 2/3, and then, following a thirty-day public comment period, in a Notice of Intent to Cancel and Position Document 4. Uses to be cancelled outright are identified for "unconditional cancellation"; those to be cancelled only if registrants object to imposition of new restrictions developed during the RPAR review are identified for "conditional cancellation." If any uses are to be retained as is, the position document so advises.

The cancellation actions described in the Notice of Intent to Cancel become effective after thirty days, unless, within that time, "a person adversely affected by the notice" requests a hearing. FIFRA §6(b). This is the old starting point for pesticide reviews. Thus, registrants and others "adversely affected" by the notice still are entitled to file objections and to initiate an administrative hearing to challenge the Agency's action as going too far. Further appeals can be taken in the courts of appeals. FIFRA §16(b). EPA Administrator Costle recently held that groups seeking to challenge a cancellation notice as not going far enough are not entitled to an administrative hearing under section 6(b). *In Re Environmental Defense Fund, et al.*, FIFRA Docket Nos. 411 *et al.* That ruling is currently the subject of litigation in federal court. *Environmental Defense Fund v. Costle*, No. 79-1971 (D.C. Cir. Aug. 24, 1979). Regardless of the outcome of this litigation, persons or groups dissatisfied with an Agency decision not to cancel a registration are entitled to seek review in the federal district courts. FIFRA §16(a).

ADVANTAGES OF THE RPAR PROCESS

The principal advantage of the RPAR process is that many pesticides can be reviewed, and appropriate regulatory actions can be formulated, without the constraints of formal adjudication before an administrative law judge. This means that the regulatory emphasis no longer need be directed toward the limited choice of whether to cancel or not to cancel the registrations of a pesticide. Instead, the RPAR process has enabled the Agency, with input from registrants and other interested parties, to pursue a much more sophisticated approach, taking into account a broad range of regulatory options short of cancellation.

For example, in the case of ZAP, an RPAR review could result in a cancellation notice initiating unconditional cancellation of the garden use and of ZAP's minor uses, but conditional cancellation of the alfalfa and rutabaga uses. The uses identified for conditional cancellation actually would be retained upon the condition that registrants agree to certain modified terms and conditions of registration. These could include reclassification of ZAP as a restricted-use pesticide for application only by certified applicators, imposition of a prohibition against applying ZAP by air within a quarter-mile of human habitations, requirement that applicators and field workers wear protective clothing and respirators while ZAP is being applied, and utilization of closed handling systems for treating rutabaga seeds with ZAP. Such limitations on future usage of ZAP are not fanciful, but are representative of the types of conditions that actually have been imposed by EPA as preconditions for retention of pesticides following RPAR review.

The RPAR process also affords to registrants an opportunity to discover and to evaluate the Agency's data on a pesticide. This could be extremely important in the event of a cancellation hearing following an RPAR review. Furthermore, long-pending proposals within the Agency to elevate the RPAR "record" into the record for subsequent cancellation hearings underscore the advantages of registrant input into the RPAR record.

AREAS FOR IMPROVEMENT

The RPAR process needs to be improved in several significant respects. RPAR reviews take too long. During the past four years approximately thirty notices of RPAR have been issued, but only a fraction of those have undergone the entire RPAR process. For those that have, the average time has been two and one-half to three years. Furthermore, there is a backlog of pre-RPAR "candidates."

Registrants and other interested parties are afforded no more than 105 days within which to respond to a Notice of RPAR and only thirty days within which to respond to a Notice of Preliminary Determination. Nevertheless, the Agency's Special Pesticide Review Division frequently takes two years to complete its rebuttal and risk/benefit analyses and six months to finalize a Notice of Intent to Cancel and Position Document 4.

Registrants who have attempted to rebut a presumption unsuccessfully are at a considerable disadvantage because the Agency will not disclose the results of its rebuttal analysis (i.e., Position Document 2) until *after* completion of its risk/benefit analysis (i.e., Position Document 3). This policy makes it difficult for registrants and other interested parties to become aware of the Agency's concerns and to provide constructive imput in a timely manner to influence the formulation of regulatory actions.

Although an RPAR is not a cancellation action, the fact that an RPAR review is being conducted does cast doubt

upon the regulatory future of a pesticide. This creates business problems for registrants and users, and provides strong justification for expedited RPAR reviews. In this regard, Congress determined in 1978 to limit RPAR reviews to those "based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment." FIFRA §3(c)(8). The Agency, however, has been lax in implementing this provision. Little, if any, information in advance of issuance of an RPAR is disclosed to registrants, as was clearly intended by Congress. Joint Explanatory Statement of the Committee of Conference on the Federal Pesticide Act of 1978, Pub. L. 95-396, at 35 (1978).

The RPAR process has enabled EPA to develop an increasingly sophisticated approach toward regulation of registered pesticides. Outright cancellation of pesticides undergoing review no longer is inevitable. Instead, under the RPAR process, the question is whether normative usage patterns can be developed so as to tip the risk/benefit balance in the direction of continued registration. This is the same fundamental consideration that in the closing days of 1979 the Agency proposed to extend to registration and reregistration of pesticides under a "registration standards system." 44 Fed. Reg. 76,312. There still is room for improvement, but the RPAR process has gone a long way in fulfilling EPA's statutory mandate under FIFRA.

Industry Intervention in EPA Litigation

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The passage of major federal environmental legislation only begins the process of establishing the scope and focus of governmental regulatory programs. Legal interpretations and policy decisions by the administering agency significantly develop the congressional framework. Those administrative determinations, in turn, are subject to change by courts in legal challenges brought by parties disagreeing with the agency. A relatively small category of those legal challenges, which have a disproportionately large impact on the shape of the regulatory programs, is environmental organization lawsuits seeking expansion of agency jurisdiction. This article discusses the importance of industry's monitoring such litigation and intervening in lawsuits that may result in additional regulatory requirements.

A dramatic example of the significant effects of environmental organization litigation involves the Environmental Protection Agency's (EPA's) regulations controlling direct discharges of pollutants into the nation's waterways. Environmental groups, dissatisfied with EPA's emphasis on regulating traditional biological pollutants rather than more exotic toxic pollutants, sued EPA in 1975 to compel promulgation of regulations that would control over 300 toxic pollutants. Recognizing the limitations of its previous regulatory efforts and the plausibility of the environmentalists' legal position, EPA entered into settlement negotiations with the plaintiffs to revise and expand its regulatory program, proposing a less expansive approach than the plaintiffs sought. A settlement agreement was ultimately reached and approved by the court. *Natural Resources Defense Council v. Train*, 8 ERC 2120 (D.D.C. 1976).

Subsequently, EPA embarked on its revised regulatory approach, which will eventually include regulations on at least 32 industry categories controlling up to 129 separate toxic pollutants, most of which had not previously been regulated. Moreover, effective and affordable monitoring methods are unavailable for many of these pollutants. The program flowing from the litigation was subsequently adopted by the Congress in the Clean Water Act Amendments of 1977. While several industry groups sought to intervene in the litigation and argue against the provisions of the settlement agreement, the momentum toward the consent decree had already been established. As a result, the restructuring of the statute's requirements, as approved by the court, was entirely the product of negotiations between the environmentalists and EPA.

The above case is one of the more significant situations where litigation brought by environmental groups against EPA resulted in court orders that establish new interpretations of environmental legislation and generally expand