Ten Years Too Late:

EPA's New Pesticide Review Rules

by Lawrence S. Ebner

EPA finally is going to update its regulations for conducting "special reviews" of pesticides under the federal pesticide law. For 10 years, EPA has shackled itself with archaic risk criteria governing initiation of such reviews.[1] When a pesticide meets or exceeds one or more of these criteria, a so-called "rebuttable presumption against registration" (RPAR) arises. The result is a comprehensive "special" review of the pesticide's risks and benefits, conducted by EPA's Office of Pesticide Programs.

Special reviews, until recently known as RPAR reviews, have been a continuing source of controversy among industry and environmental groups. In many cases, the reviews have been initiated on the basis of scant toxicological data, have dragged on for years in a seemingly arbitrary and secretive manner, and have led to cancellation or restriction of highly beneficial pesticides. In an effort to enhance the credibility of the program, EPA now has proposed regulations[2] intended to modernize the criteria for conducting special reviews and establish more and expeditious procedures.

Roots of the Problem

FIFRA—the Federal Insecticide, Fungicide, and Rodenticide Act—was enacted in 1947 as a licensing and labeling statute for "economic poisons." The generally benevolent U.S. Department of Agriculture administered the Act until 1970, when the newly-created EPA assumed responsibility. Two years later, in response to growing environmental concerns, Congress comprehensively rewrote FIFRA to give EPA broad authority to assess the effects of pesticides on man and the environment and to regulate their use. This seminal legislation, the Federal Environmental Pesticide Control Act of 1972 (FEPCA, Pub. L. No. 92-516) transformed FIFRA from a simple labeling law into a comprehensive regulatory statute.[3]

FEPCA established a new statutory standard for registration of pesticides: a pesticide could be registered only if it would "perform its intended function without unreasonable adverse effects on the environment." The term "unreasonable adverse effects" was defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental *costs and benefits* of the use of any pesticide." Thus, under the amended FIFRA, a pesticide cannot get registered, or stay registered, if the risks of use outweigh the benefits of use.

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As part of the FEPCA amendments, Congress directed EPA to review the thousands of pesticides that had been registered prior to 1972 and to reregister only those that do not violate the unreasonable adverse effects standard. This is an enormous managerial task which 13 years later, EPA has just begun to address in a systematic manner through a generic registration standards program.

To address more immediate concerns, Congress in FIFRA Section 6(b) authorized EPA to cancel or restrict the use of any registered pesticide which, "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment."

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Before cancellation or restriction can go into effect, however, registrants and other adversely affected parties such as pesticide user groups have the right to challenge the proposed action in a full-blown adjudicatory hearing before an EPA administrative law judge.

Birth of the RPAR

In the early and mid-1970s, EPA was eager to begin carrying out its mission under FIFRA. The agency's plan was to take action against widely-used but environmentally persistent or highly toxic pesticides, especially those in the organochlorine family. As the lengthy DDT, aldrin/dieldrin and heptachlor/chlordane cancellation hearings had demonstrated, however, it would be virtually impossible for EPA to leap head first into contemporaneous cancellation proceedings on the 40 or 50 pesticides at the top of the agency's "problem" list. Instead, EPA needed a way to identify those which posed a "substantial question of safety" warranting issuance of a cancellation notice.[4] In July 1975 EPA devised the rebuttable presumption against registration as a mechanism for identifying such pesticides.

During the past decade, the RPAR process has evolved into much more than a screening device for cancellation notices. By the late 70s and early 80s, EPA had matured sufficiently to move away from a black-and-white approach to pesticide regulation. Moreover, the agency came to realize that adjudicatory proceedings are an undesirable way to elicit scientific data about the risks and benefits of a pesticide. As a result, RPAR reviews grew into a relatively informal, non-adjudicatory (but often adversarial) procedure for collecting or generating data on the risks and benefits of the principal uses of a pesticide. The RPAR itself became the vehicle for deciding what additional safeguards (e.g., label warnings, protective clothing, restricted use classification) could be imposed to shift the risk-benefit balance toward continued registration rather than cancellation of a pesticide.

'Industry likened issuance of an RPAR to a criminal indictment'

Because RPAR reviews have become such a critical factor in the regulatory fate of so many pesticides, EPA finally has recognized that reforms are essential if the program is to remain viable.

What's In A Name?

The term "rebuttable presumption against registration" was coined at a time when EPA's objective in conducting reviews was to cancel as many older pesticides as possible. Although a pesticide could continue to be sold and used while undergoing RPAR review, industry likened issuance of an RPAR to a criminal indictment, and repeatedly voiced concern that the term would be widely misinterpreted by the public and foreign governments as a cancellation action.

Congress began to take a critical look at the RPAR process in 1978. It took EPA another five years, however, to drop the term "RPAR" and begin using

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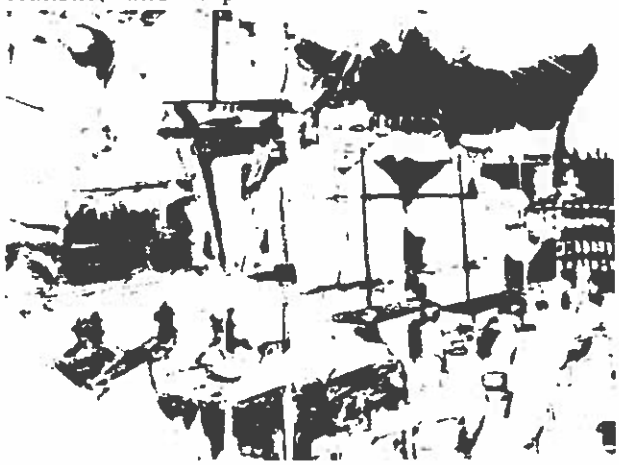
"special review" instead. The name change is used throughout EPA's proposed regulations. According to EPA, the term "special review" is intended "to indicate that the use of a pesticide may pose a significant risk, and, therefore, the agency will perform an indepth review of the risks and benefits of the pesticide use before deciding what regulatory action, if any, is appropriate." The change in terminology perhaps will help neutralize the stigma of undergoing what in substance remains an RPAR review.

Revised Risk Criteria

At the center of EPA's RPAR reform regulations are the revised risk criteria. As do the existing criteria, the revised criteria encompass chronic effects such as oncogenicity, teratogenicity, fetotoxicity and mutagenicity, and acute effects to humans, domestic animals, and wildlife. There are significant differences, however, between the old and the new. In EPA's words, the old criteria set forth at 40 C.F.R. Section 162.11(a) are "inflexible," "unclear," "unrealistic," and "impractical."



The principal defect in the existing criteria is that they do not take into account "whether exposure to humans or other nontarget species is high enough to pose a significant risk." In 1978, Congress, in a Conference Committee report, directed EPA "to consider exposure to a pesticide before initiating the RPAR process." It took EPA another seven years to finally get the message. Thus, the new criteria are intended to assure "that there is a risk based not only on the toxic effect associated with a pesticide but also on the likely exposure to the pesticide. . . ."

For example, the existing RPAR criterion on oncogenicity is triggered if a pesticide "[i]nduces oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation or dermal exposure." In contrast to this vague standard, EPA's proposed revised criterion covers oncogenic, teratogenic, fetotoxic, reproductive, and other chronic or delayed toxic effects (except heritable genetic effects covered by a separate criterion), and it would take actual levels of exposure from pesticide use into account:

> The Administrator may conduct a special review of a pesticide use if he determines, based on a validated test or other significant evidence, that the use of the pesticide (taking into account the ingredients, impurities, metabolites, and degradation products of the pesticide):
>
> . . . .
>
> (b) May pose a risk of inducing in humans an oncogenic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect, *which risk is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk*, based upon:
>
> (1) Effects demonstrated in humans or experimental animals.
>
> (2) *Known or predicted levels of exposure* of various groups of humans.
>
> (3) The use of appropriate methods of evaluating data and relating such data to human risk.
>
> *(emphases added)*

Similarly, with respect to hazards to wildlife, the existing criterion is confusingly expressed in terms of theoretical calculations of post-application residues in food or feed which exceed the acute oral LD_{50} for a representative mammalian species. The new criterion, on the other hand, would authorize a special review only if "the use of a pesticide . . . may *result in residues in the environment* of nontarget organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms." (emphasis added) Again, the emphasis is on actual exposure to pesticides or their residues.

The practical significance of these and the other revised criteria is that special reviews will be harder to trigger than they have been in the past. The mere potential of a pesticide to produce toxicological effects in humans or animals will not be enough. However, because actual exposure to a pesticide will be taken into account in assessing risk once one or more of the new criteria are met, the rebuttable presumption against registration should be tougher to rebut than under the old standards.

'Open' Reviews

EPA's proposed regulations also for the first time describe in detail the actual procedures EPA would use in conducting special reviews. The existing

RPAR regulations barely address procedural matters. Instead, RPAR procedures have evolved almost entirely as a matter of internal agency practice.

The key procedural issue addressed by the new regulations is the openness of the review process. EPA traditionally has taken the position that RPAR review is a non-statutory procedure conducted for the agency's own benefit, and that any outside input is wholly gratuitous on the part of the agency. In the past, EPA has established short periods for public comment on staff position documents that initate reviews or describe preliminary determinations, but most of each review has been conducted in secret. In some cases, the agency has maintained silence for years between initiation of an RPAR and a preliminary determination, or between a proposed and final regulatory decision. The new regulations, however, are supposed to open up the decisionmaking process. According to EPA, "the goals of openness, speed, scientific accuracy, and candor will be achieved by the new procedures."

When the Reagan Administration assumed control of EPA in 1981, one of the first priorities was to conclude the numerous RPARs that had been begun during the Carter years. The Reagan EPA sought to end the RPARs through "negotiated settlements" with industry and user groups. A typical settlement would involve an agreement by industry to accept new restrictions on a pesticide's use and to conduct further testing on the pesticide, in return for EPA's concluding the RPAR review promptly and without cancellation of registrations.

Environmental groups such as the Natural Resources Defense Council, which had wielded considerable influence at EPA during the Carter Administration, felt disenfranchised. NRDC and the AFL-CIO, after the departure of EPA Administrator Anne Burford and her assistants in the spring of 1983, filed suit against EPA. They claimed that RPAR settlements and other key pesticide decisions reached during the first two years of the Reagan Administration had been unlawfully negotiated with industry behind closed doors.[5]

The post-Burford EPA treated NRDC's action as a "friendly" lawsuit. The agency's pesticide staff was eager to distance itself from the policies of Mrs. Burford, and was only too happy to cooperate with NRDC. EPA spent a year virtually cleaning out its file cabinets for NRDC on numerous pesticide decisions, turning hundreds of highly sensitive documents over to NRDC and to the AFL-CIO. Finally, despite its supposed aversion to "closed door" meetings, NRDC engaged EPA in its own closed-door negotiations to settle the suit (industry intervenors were rebuffed by NRDC and EPA when they asked to participate in the discussions). In the resulting "sweetheart" deal between EPA and NRDC, EPA agreed to reconsider numerous RPAR decisions and propose regulations ensuring openness in future reviews.

The special review regulations being proposed by EPA incorporate the terms of the settlement agreement with NRDC. Under the new regulations, industry groups still will be able to meet in private with EPA "to obtain information, exchange views, explore factual and substantive positions, or discuss regulatory options concerning Special Review decisions," but a memorandum of each such meeting will be placed into a public docket. Furthermore, during such meetings, "the agency will not commit to take any particular action concerning a pending decision." According to EPA, these and similar procedures will ensure that "the public will have full access to and play a vital role in the decision making process."

The Future

EPA has major plans for the pesticides special review program. Basically, the agency would like to elevate the review process into an informal rulemaking proceeding by which pesticide producers and users could provide input into the decisionmaking process, but, pursuant to statutory changes, would lose the right to challenge the final regulatory decision in an administrative hearing. Instead, they would have to go to court, where the standard of review would be considerably narrower.

The first step in insulating EPA regulatory decisions from intensive judicial scrutiny?

Ironically, by purporting to open the special review process, EPA actually may be taking the first step in insulating its regulatory decisions from intensive judicial scrutiny. Under the current cancellation provisions of FIFRA, pesticide producers and users have the right to an administrative hearing at which EPA staff must appear and explain to an administrative law judge the bases for their findings and determinations. Informal rulemaking, however, would allow those same personnel—the EPA decisionmakers—to remain anonymous.

EPA clearly has taken an important step in improving the special review process itself. The regulated community, however, should be wary of future EPA proposals for "open" pesticide decisionmaking. □

FOOTNOTES

[1] *See 40 C.F.R. Section 162.11(a).*

[2] *50 Federal Register 12188.*

[3] *See generally* Ruckelshaus v. Monsanto Co., *104 S.Ct. 2862, 2867 (1984).*

[4] *See* Environmental Defense Fund v. Ruckelshaus, *439 F.2d 584 (D.C. Cir. 1971).*

[5] Natural Resources Defense Council, et al. v. EPA, *Civil Action No. 83-1509 (filed D.D.C. May 26, 1983).*