UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of	)	
	)	
Rohm & Haas Company,	)	FIFRA Docket No. 613
	)	
Petitioner	)	

Federal Insecticide, Fungicide and Rodenticide Act - Conditional Registrations - Denial of Registration - Entitlement to a Hearing

Where the Agency had concluded a special review of dicofol pesticides in May of 1986, setting forth requirements for the continued registration of such products and it was undisputed that Petitioner's technical dicofol complied with those requirements and was substantially similar within meaning of § 3(c)(7)(A) to a currently registered technical dicofol product and presented no significantly different qualitative risk compared to currently registered pesticides, letter, stating in effect that Agency needed a minimum of six months to reconsider risks of dicofol and reinitiate consultation with the Office of Endangered Species prior to decision on application for registration, was held to be a denial of registration, entitling Petitioner to a hearing in accordance with §§ 3(c)(6) and 6(b) of the Act, notwithstanding failure to follow procedural requirements for denial established by § 3(c)(6) of Act, and regulation, 40 CFR § 162.7(f).

Federal Insecticide, Fungicide and Rodenticide Act - Conditional Registrations - Special Review - Incremental Risk

Where it was undisputed that Petitioner's product met all of requirements for continued registration determined after conclusion of special review and Agency conceded Petitioner's product presented no significantly

different qualitative risk compared to currently registered pesticides and Agency's published policy (47 FR 57624 (1982) and 48 FR 34000 (1983)) is not to conduct incremental risk assessments for identical or substantially similar products, because, inter alia, granting additional registrations for such products would not increase pesticide usage, Agency's refusal to approve application for conditional registration complying with requirements for conditional registration in 40 CFR § 162.167(a), while it conducted incremental risk assessment to determine whether granting the registration would expand use and risks of the pesticide, was held to be improper as a perpetuation of double standard conditional registration was designed to prevent.

Federal Insecticide, Fungicide and Rodenticide Act - Conditional Registration - Special Review - New Information

Where it was undisputed that Petitioner's product met all requirements for continued registration enunciated after conclusion of special review and Agency conceded Petitioner's product presented no significantly different qualitative risk compared to currently registered pesticides and application appeared to comply with all requirements for conditional registration set forth in 40 CFR § 162.167(a), Agency's refusal to approve registration while it studied alleged new information as to risks of pesticide and reinitiated consultation with Office of Endangered Species was held to be improper, where Agency, in effect, acknowledged new information would not, at present, warrant initiation of special review in accordance with § 3(c)(8) of Act.

Federal Insecticide, Fungicide and Rodenticide Act - Rules of Practice - Accelerated Decisions

Provision in Rules of Practice (40 CFR § 164.91) that ALJ may render accelerated decision in favor of Respondent appears designed only to preclude dismissal in Petitioner's favor without a hearing and was held not to be a bar to an accelerated decision for Petitioner, where it appeared that no material facts were in dispute and that, as a matter of law, Petitioner was entitled to have its application for registration approved.

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Appearance for Respondent: William L. Jordan
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OPINION AND ORDER
DENYING MOTION TO DISMISS AND
GRANTING MOTION FOR AN ACCELERATED DECISION

This is a proceeding under § 6(b) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136d) to require the conditional registrations of dicofol products manufactured and marketed by Rohm & Haas (Petitioner) under the trade name Kelthane.

The specific product at issue is Kelthane Technical.[1/] Petitioner alleges and Respondent denies that the registration has been denied. The following recitation of facts, culled principally from Petitioner's motion for an expedited hearing and an accelerated decision and accompanying exhibits, filed February 26, 1987, appears to be largely undisputed.

Rohm & Haas' Kelthane products have been registered under FIFRA for over 30 years, having been first registered in 1956. The principal uses of dicofol pesticides are as a miticide on cotton in California and on citrus in Texas and Florida. More than 75% of Petitioner's sales and uses of such products are in April, May and June. Approximately 80% of these sales are of Kelthane MF. Rohm & Haas appears to have enjoyed approximately 80% of the market for dicofol pesticides. The only current registrant of a technical dicofol product is Makhteshim-Agan (America), Inc., an Israeli company, which sells technical dicofol for conversion into end-use products.

Because of concerns over its DDTr[2/] content, EPA began a Special Review of dicofol in December 1983. Notice of the initiation of the Special Review was published on March 21, 1984 (49 FR 19569). On October 10, 1984,

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1/ Although Rohm & Haas asks for the entry of an order granting registrations of Kelthane Technical and Kelthane MF, an agricultural miticide formulated from Kelthane Technical, the registration package for Kelthane MF was apparently not completed until February 26, 1987 (Affidavit of Edwin F. Tinsworth, Director, Registration Division, dated March 13, 1987, Attachment 2 to Respondent's Motion To Dismiss and Opposition To Petitioner's Motion For Expedited Hearing and Accelerated Decision). Rohm & Haas has also filed applications for the registration of five other products formulated from Kelthane Technical. These applications are conditioned upon the registration of Kelthane Technical and will be completed if, and when, the mentioned product is registered.

2/ DDT and related impurities are referred to as DDTr.

EPA published Proposed Notice of Intent To Cancel Registration of Pesticide Products Containing Dicofol (49 FR 39820). Rohm & Haas participated actively in the Special Review process while Makhteshim relied on Rohm & Haas' presentation. The Special Review process included consultation with the Office of Endangered Species (OES) of the Department of Interior.

On August 13, 1984, OES issued a biological opinion concluding that the use of dicofol was likely to jeopardize the continued existence of the endangered peregrine falcon. EPA and the Scientific Advisory Panel (SAP) considered this opinion, and data from the registrants to the effect that within approximately two years after conclusion of the Special Review, the DDTr content of dicofol could be reduced to 0.1 percent. EPA concluded that if this were accomplished, the benefits of continued use of dicofol would outweigh the risks. EPA reinitiated consultation with OES and after lengthy consideration and reconsideration, which it is unnecessary to recount here, OES issued a revised biological opinion in March of 1986. The opinion concluded that in all parts of the U.S., except California, jeopardy to the peregrine falcon could be avoided by reducing the DDTr contamination levels to 0.1 percent or less no later than December 31, 1988, after which only dicofol containing 0.1 percent or less DDTr could be sold. With respect to the use of dicofol in California, OES determined that either the use of all such products containing more than 0.1 percent DDTr should be banned immediately or to compensate for the negative effects of continued use of dicofol having a DDTr content in excess of 0.1 percent during the period until the use of such products were prohibited, dicofol manufacturers should be required to fund a

portion of the nest manipulation work of the Santa Cruz Predatory Bird Research Group (SCPBRG).3/ EPA terminated the Special Review on May 29, 1986 (51 FR 19508-25), finding that dicofol products can meet the statutory standard for continued registration, provided the level of DDTr contamination was initially reduced to less than 2.5 percent and thereafter to 0.1 percent or less and the labels of dicofol were amended to require the wearing of gloves while handling the product (Id. at 19517). Registrants were required to immediately amend their registrations to certify an upper limit of DDTr contaminants equivalent to 2.5 percent (or less) of the technical grade material. Continued sale and distribution of dicofol containing between 0.1 percent and 2.5 percent DDTr was allowed until December 31, 1988. Registrants were informed that they had 30 days from publication of the notice in the Federal Register or receipt of the notice, whichever was later, to amend their confidential statements of formula to establish an upper certified limit of DDTr equal to or less than 2.5 percent of the amount of technical grade dicofol in the product. Confidential statements of formula were to be accompanied by information showing that the registrant can produce the product with no more DDTr than the amount certified as the upper limit. Registrants were informed

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3/ To assist the recovery of peregrine falcons, SCPBRG removes eggs laid in the wild, artificially incubates the eggs and releases the hatchlings into falcon nests. OES indicated that $25,000 in 1986 and $75,000 for each of the following four years would be sufficient. Rohm & Haas and Makhteshim agreed to furnish these sums in equal shares and on May 15, 1986, entered into an agreement to provide such funding with EPA and The Peregrine Fund, Inc., agent for SCPBRG.

that if the applications were otherwise acceptable, applications would be approved conditionally.4/

Rohm & Haas supplied EPA with an amended confidential statement of formula and supporting product chemistry along with certification of compliance with the 2.5% DDTr standard. The product chemistry statement apparently included newly identified impurities in Kelthane Technical. According to Rohm & Haas, EPA had not previously defined or considered these impurities as DDTr. Also, according to Petitioner, EPA redefined DDTr to include these impurities without notice to it, and by letter, dated September 24, 1986, informed Rohm & Haas that its registrations had been canceled by operation of law as of June 29, 1986, for failure to comply with the less than 2.5 percent DDTr requirement. Although Petitioner did not agree with EPA's conclusion as to the DDTr content of Kelthane Technical,5/ it took immediate steps to reduce all impurities in Kelthane Technical to the less than 2.5 percent limitation for DDTr as defined by EPA.

4/ 51 FR 19518. The notice further stated that "EPA is particularly concerned that dicofol independent of the effect of DDTr contaminants, may pose a risk to the environment. If this is confirmed or if new data strengthen the evidence of the carcinogenicity of dicofol, EPA will consider further regulatory action." (Id.) These concerns were based in part on a "small body of data" suggesting that dicofol may be metabolized by some avian species to DDE or that dicofol, itself, may cause eggshell thinning (Id. at 19512).

5/ If inclusion of the impurities as DDTr were, in fact, a redefinition, without notice to Petitioner, the contention that the registrations were canceled by operation of law as of June 29, 1986, is questionable indeed. Rohm & Haas has, however, acquiesced in the cancellations and their propriety is not in issue here.

On October 17, 1986, Petitioner filed the applications for conditional registration referred to at the beginning of this opinion. By letter, dated December 5, 1986, EPA's Product Manager for Dicofol, Dennis E. Edwards, Jr., informed Rohm & Haas that "[w]e have completed our review of your application for registration of the subject product [Kelthane Technical]." The letter, however, requested additional product chemistry data and other information, which Rohm & Haas appears to have satisfactorily supplied by letters, dated December 11 and 15, 1986. Enclosed with Mr. Edwards' letter was a copy of a memorandum, dated November 21, 1986, from Ms. Susan V. Hummel, Chemist, through Edward Zager, Section Head, Residue Chemistry Branch, Hazard Evaluation Division, which reviewed Petitioner's product chemistry. The memorandum states that "Kelthane Technical is similar to, but not identical to Mitigan Technical [Makhteshim's product]. The two products contain differing amounts of the active ingredients and impurities. We defer to TOX and EEB for incremental risk assessments of these differences. No further information is required, TOX and EEB considerations permitting."

Rohm & Haas asserts (Motion at 11), that the Registration Division determined not to conduct an incremental risk assessment, because the differences between the two products are minor and pose no incremental

risk to the environment.6/ The Agency claims that its attempt to determine whether granting Petitioner's application would increase the overall use of dicofol is an incremental risk assessment.7/

On December 30, 1986, Rohm & Haas submitted 62 studies in response to EPA's data call-in of December 1983. These studies were not submitted to comply with any requirement for conditional registration. According to Rohm & Haas, the studies relate to risks of using dicofol having no more than 0.1 percent DDTr, present no information regarding differential risks of Petitioner's and Makhteshim's dicofol products and provide no information indicating that Kelthane Technical or Kelthane MF fail to comply with requirements for conditional registration.

6/ The preamble to the proposed regulations governing the conditional registration of pesticides (47 FR 57624, et seq.) (1982) states that the concept of incremental risk assessment is central to the conditional registration program (Id. at 57626). Conditional registration addresses the incremental risks of a proposed product or use, while risks associated with current uses of a pesticide are addressed through the registration standards program and, if necessary, the Rebuttable Presumption Against Registration (RPAR), now Special Review, program. The concept is that the risks and benefits of conditionally and previously registered pesticides will be assessed at the time a registration standard is developed. In explaining the test to be employed in determining whether an application for conditional registration complied with the requirement of § 3(c)(7)(A) that the new product or use "would not significantly increase the risk of unreasonable adverse effects on the environment," the Agency indicated that the focus would be on any increased exposure that might result from conditional registration of the pesticide (Id. at 57626-27). It was further stated that "[i]ncremental risk becomes significant only when conditional registration would involve either exposure to non-target populations not previously exposed, or increased exposure to the populations that are at risk from current pesticide usage." Because the market for a particular pesticide is considered essentially finite, the Agency made it clear that granting additional registrations for identical products would not increase the usage of such pesticides or increase exposure risks (Id. 57627).

7/ Statement of William L. Jordan, counsel for Respondent at the second prehearing conference, held March 23, 1987.

By letter, dated January 27, 1987, the Director of the Registration Division, Edwin F. Tinsworth, informed Rohm and Haas that:

> "We have completed a preliminary review of the additional physical chemistry information (vapor pressure and melting point) submitted in support of the subject product.
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> On December 30, 1986 your company submitted a number of studies in response to the registration standard for dicofol issued December 30, 1983. We have determined that some of these studies need to be reviewed prior to our decision regarding the registerability of the subject product. We believe a review of these data is prudent because they provide us with new information which should answer some of our concerns regarding the impact of dicofol on the environment.
>
> In addition, EPA has previously consulted with the Department of Interior's Office of Endangered Species (OES) concerning dicofol. Since EPA has received new data, we believe it is appropriate to reinitiate consultation in this matter.
>
> We anticipate our review will take approximately 5 months to complete. The OES consultation as you are aware could take up to six months after we have initiated the consultation."

The position stated in the referenced letter was reaffirmed by the Director of Office of Pesticide Programs on February 6, 1987, and by the Assistant Administrator for Pesticides and Toxic Substances on February 13, 1987.8/ Makhteshim's dicofol product, Mitigan Dicofol Technical, continues to be registered and it is undisputed that there are no

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8/ In a letter, dated February 19, 1987, to Mr. Blaine H. Holcomb, an operator of an orchard and nurseries in Mission, Texas, responding to concerns over the availability of Kelthane miticide for the current season, the Assistant Administrator for Pesticides and Toxic Substances, John A Moore, stated that "* * the Agency has obtained new information indicating that dicofol itself causes eggshell thinning, and thus may pose unreasonable risks to the environment." Mr. Holcomb was informed that until the Agency completes its review of pertinent data, there would be no new registrations of any products containing dicofol as the active ingredient, regardless of the level of DDT and related contaminants contained therein. The letter pointed out, however, that one product containing dicofol (Lanco Dicofol 4 RC) remains registered for post-bloom (March 15 - May 1) control of the citrus rust mite.

significant differences between Makhteshim's product and Kelthane Technical.9/ Petitioner says that it has been informed by Makhteshim that Makhteshim will take steps to supply all domestic dicofol needs if Kelthane is not registered.

Respondent concedes that Petitioner's Technical dicofol appears to pose the same qualitative risk as Makhteshim's product (Opposition at 15). Based on information from Rohm & Haas, it asserts, however, that Makhteshim, and registrants formulating end-use products from its product, Mitigan Technical, would, at best, be able to supply less than half of the U.S. demand for dicofol. Alluding to Rohm and Haas' alleged claim that it will be able to satisfy any demand for dicofol not filled by Makhteshim, Respondent states that it is attempting to determine whether the expansion in the use of dicofol that would likely result from granting Petitioner's application would constitute a significant increase in the risk of unreasonable adverse effects on the environment.

As indicated (note 4, supra), Respondent had concerns over the environmental effects of dicofol independent of its DDTr content prior to conclusion of the Special Review. Since that time Respondent has received information based on studies involving screech owls and ring doves, which purport to show that dicofol having a DDTr concentration of less than 0.1 percent caused the laying of fewer and thinner eggs.10/

9/ EPA has acknowledged that Kelthane is substantially similar to the currently registered product, Mitigan Technical and its use or uses, within the meaning of § 3(c)(7)(A) (Affidavit of Edwin F. Tinsworth at 3).

10/ Although EPA had preliminary information on the results of these studies prior to the conclusion of the Special Review, the screech owl study has apparently yet to be completed in final form (Affidavit of Larry W. Turner, a biologist in the Office of Pesticide Programs, Attachment 1 to Opposition).

Another study, based on 28 days of exposure to dicofol by bluegill sunfish, reported dicofol concentrations 10,000 times higher than the ambient water concentration and, that an equilibrium concentration had not been reached. Still another study involving rats led to the conclusion that dicofol and its technical formulation are powerful inducers of hepatic mixed function oxidases and, because other studies had associated reproduction alterations in birds exposed to DDT, PCBs, or dieldrin with decreased estrogen levels resulting from induction of monooxygenases, it was suggested that the effects of induction may be as important as eggshell thinning in the population declines of some raptor species.11/ These studies assertedly increased EPA's concerns as to the risks of dicofol.

Respondent says that it is reviewing on an expedited basis the four mentioned studies and a number of other studies submitted by Rohm & Haas in December 1986 in response to the registration standard. These studies involve, inter alia, the fate of dicofol in the environment and the potential for dicofol to harm non-target wildlife. The review involves over 40 studies and is scheduled for completion on May 27, 1987. Respondent notes, however, that additional time will be needed to review a final report on one of the studies, apparently involving ring doves (note 10, supra), from the University of California at Davis, which is not presently

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11/ Rohm & Haas says that the bio-concentration or accumulation study merely confirms information known to the Agency from previous studies and that the results of the University of California at Davis study discussing hepatic microsomal metabolism have been known for at least two decades (Petitioner's Opposition To Respondent's Motion To Dismiss and Reply To Respondent's Opposition To Motion For Expedited Hearing and Accelerated Decision, dated March 18, 1987, hereinafter Petitioner's Reply, at 36, 37). In fact, Rohm & Haas asserts that it submitted data concerning hepatic microsomal metabolism to the Agency in 1984.

available. On March 3, 1987, EPA reinitiated consultation with OES, which under its regulations, has 90 days in which to respond.

Respondent estimates that it may be in a position to determine whether to approve or deny Rohm & Haas' application by the fall of 1987 (Tinsworth Affidavit). It cautions, however, that the data may be inconclusive as to the registrability of Kelthane and that additional data may be necessary. Respondent also points out that its data reviews and the OES response may indicate the need for labeling changes.

ARGUMENTS OF THE PARTIES

Rohm & Haas contends that it has complied with all of the requirements for conditional registration of Kelthane Technical, that the Agency has unlawfully denied its application and that this denial, while at the same time allowing the continued registration of Mitigan Technical, perpetuates the very double standard the conditional registration process was designed to prevent.

Section 3(c)(7)(A) of the Act (7 U.S.C. § 136a) provides:

> "(7) Registration under special circumstances--Notwithstanding the provisions of subsection (c)(5) of this section--
>
> (A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any"

> "unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under subsection (c)(5) of this section: Provided, That, if the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act."

Implementing regulations (40 CFR § 162.167(a)) set forth four requirements for the approval of conditional registration.12/ It is undisputed that Petitioner's application complies with three of these requirements and the only requirement at issue here is § 162.167(a)(3), i.e., "[t]he use of the product will not cause a significant increase in the risk of unreasonable adverse effects on the environment."

12/ Section 162.167(a) provides:

> (a) Criteria for approval of conditional registration. The Agency will approve a request for conditional registration under FIFRA Sec. 3(c)(7)(A) or (B) if it determines that, when considered with any restrictions or conditions imposed:
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> (1) The product is not misbranded, as defined in FIFRA Sec. 2(q), and its labeling complies with § 162.10; and
>
> (2) The test data and other materials required to be submitted comply with the requirements of the Act, § 162.163, § 162.165, and Agency procedures;
>
> (3) The use of the product will not cause a significant increase in the risk of unreasonable adverse effects on the environment; and
>
> (4) Any tolerance, food additive regulation, exemption or other clearance required by the Federal Food, Drug, and Cosmetic Act (including clearance for pesticide uses which are also drug uses) has been obtained.

Rohm & Haas asserts that EPA has already concluded in the Special Review that Kelthane will not cause a significant increase in the risk of unreasonable adverse effects on the environment (Motion at 28). Moreover, it argues that EPA has no sound basis for concluding otherwise. Citing National Coalition Against The Misuse Of Pesticides v. Thomas, _____ F.2d _____ (D.C. Cir. 1987), Petitioner says that EPA may not alter the requirements for continued registration of products containing dicofol, reached after a lengthy special review, without a reasonable factual basis for doing so. Rohm & Haas asserts that it is unaware of any facts upon which EPA could base a determination that the 1986 registration standard for dicofol is no longer valid and that, in any event, EPA would have to modify the decision in accordance with special review procedures.

Rohm & Haas points out that EPA performs an incremental risk assessment to determine whether the use of a pesticide will cause an unreasonable risk of adverse effects on the environment and that no incremental risk assessment is performed where a product is identical to a currently registered product (note 6, supra). This is because the market for pesticides is considered to be finite and granting additional registrations for identical products would not increase pesticide usage or exposure thereto. Although Kelthane Technical is not identical to Mitigan Technical, it is undisputed that the differences are minor.13/

13/ Dr. Robert H. Larkin, Manager of the Agricultural Chemicals Registration and Regulatory Affairs Department for Rohm & Haas, states the dicofol products of his company and those of Makhteshim are substantially similar and have essentially the same labels and uses (Exh 2 at 11). See also Hummel memorandum, ante at 8. The preamble to the final regulation on Conditional Registration (48 FR 34000-007, July 26, 1983), provides that the Agency would not require additional data to approve the registrations of substantially similar products (Id. at 34003).

Supporting its motion to dismiss, Respondent points out that a denial is a statutory prerequisite to a hearing (§ 3(c)(6)) and argues that, because there has been no denial, there can be no hearing. It contends that a refusal to register pending a review of data does not constitute a denial and that Congress clearly did not mean to provide a right to a hearing to every applicant who receives notice that the Agency will not act on an application within the applicant's time frame. Respondent says that the conditional registration regulation reflects the distinction between review and denial, pointing out that 40 CFR § 162.167(e)[14/] provides for denial in two instances: where the application for conditional registration fails to meet any of the requirements of § 162.167(a) or, if there are insufficient data to make the required determination. It argues that both grounds require a determination which cannot be made until necessary data reviews are complete.

Respondent says that it is concerned approval of Petitioner's application would result in the use of between two to five times as much dicofol as would take place, if the product were not registered.[15/] It asserts

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14/ Section 162.167(e) provides:

> (e) Denial of conditional registration. The Agency will deny conditional registration if the application for conditional registration fails to meet any of the requirements of § 162.167(a) or if there are insufficient data to make the required determination. Denial of conditional registration will be in accordance with the provisions set forth in § 162.7(f)(1) through (4).

15/ Responding to a comment which had objected to the suggestion that EPA might require the submission of marketing analyses or projections for a product for the purpose of assessing increased exposure from its registration, EPA stated "While fully recognizing that marketing projections are speculative and subject to possible error, the Agency believes that it is sound policy to require such information when no better data are available to evaluate the increase in exposure which is often an important part of the assessment of incremental risk." (48 FR 34002).

that such an expansion of use of dicofol would significantly increase the risks of unreasonable adverse effects, if dicofol, itself, is likely to cause adverse effects on the environment. In view of the studies alluded to, ante at 10, 11, indicating adverse effects from dicofol exposure, Respondent says that concern for protecting the environment requires an attempt to evaluate whether environmental levels of dicofol will be sufficiently high to cause any of the adverse effects indicated by the new studies. Respondent argues that such an evaluation is consistent with the statute and regulations.

Respondent disputes Petitioner's contention that EPA's finding of substantial similarity between Kelthane Technical and the currently registered product, Mitigan Technical, constitutes, in effect, a finding that registration of Kelthane will not cause a significant increase in the risk of unreasonable adverse effects on the environment (Opposition at 22). It points out that the statute (§ (3)(c)(7)(A)) requires the Agency to make two separate determinations, both of which require a finding that approval of the application would not lead to a significant increase in the risk of adverse effects on the environment and that only the first of these, § (3)(c)(7)(A)(i), involves a comparison of the applicant's product with currently registered products. Respondent asserts that § 3 (c)(7)(A)(ii) requires the Agency to go beyond a comparison of product composition and compels the consideration of other ways in which registration of Kelthane Technical might increase the risk of unreasonable adverse effects on the environment. It argues that clearly one way in which a decision to register Kelthane Technical might increase this

risk is by expanding the amount of dicofol being used, therefore, being placed into the environment. According to Respondent, it is entirely consistent with the statute for EPA to consider dicofol usage in assessing its risks prior to acting on Petitioner's application. As indicated, ante at 11, Respondent disputes Makhteshim's capacity to supply all domestic dicofol needs.

Acknowledging that the purpose of conditional registration is to eliminate the double standard between the treatment of new applications and current registrations of substantially similar products, Respondent points out that the plain language of § 3(c)(7) requires the Agency to base the decision as to whether to conditionally register a pesticide on the risks of unreasonable adverse effects on the environment and that this purpose must take precedence over the anticompetitive effects of which Rohm & Haas complains. Respondent also acknowledges that generally EPA's policy is to regard additional conditional registrations as leading only to a redistribution of an existing market rather than an increase in use, but contends that the assumption there will be no increase in exposure appears inappropriate and that accordingly, the policy described in the preamble (note 6, supra) need not be followed.

Emphasizing that it is well established that an Agency may change its position, if warranted by new information, Respondent refers to the assertedly new information as to the risks of dicofol obtained since the conclusion of the Special Review, and rejects, as patently incorrect, Petitioner's contention the Agency is required to conditionally register products complying with the notice of May 29, 1986 (Opposition at 24).

Respondent reiterates the assertion that it is appropriately reviewing Petitioner's application to determine whether it meets the criteria for conditional registration, argues that such a review does not constitute a denial of registration and that, until EPA determines either that Rohm & Haas has not satisfied the criteria for registration or, that the Agency needs additional data to decide that question, Rohm & Haas has no grounds for an adjudicatory hearing under FIFRA. Relying on the Tinsworth affidavit, Respondent claims that a decision Petitioner was entitled to a hearing based on the letter, dated January 27, 1987, could severely disrupt the pesticide registration program by diverting limited resources to conducting hearings rather than consideration of applications and other regulatory actions (Opposition at 25).

Respondent contends that the Tinsworth letter is nothing but a status report and not a denial of registration, because it was not proceeded by a notification of intent to deny, it was not published in the Federal Register, and lacks information required by regulation to appear in a notice of denial.16/ According to Respondent, it is obvious that the January 27, 1987, was not intended as a denial.17/

16/ Such information includes the product name, name and percentage by weight of each active ingredient, proposed patterns of use and proposed classification (40 CFR § 162.7(f)(3)).

17/ Opposition at 27. Respondent states that Petitioner has not alleged and the record would not support a finding that EPA was unreasonably withholding a notice of denial after a determination that the application will not be approved. Moreover, Respondent says that even if such a situation existed, it is questionable whether Rohm & Haas could compel a hearing under FIFRA.

Even if a denial is found and Rohm & Haas' request for a hearing granted, Respondent says that at least the following facts are in dispute and that the schedule sought by Petitioner (a decision by March 30, 1987) cannot be met:

"1) Makhteshim and its formulators will be unable to supply enough dicofol to meet substantially all of the U.S. demand for the pesticide;

2) New information has been received by EPA since the May 1986 Notice of Intent to Cancel raising serious concerns about possible adverse effects on the environment from dicofol, itself;

3) New information regarding the possible adverse effects of dicofol on the environment raise legitimate concerns about a potentially significant increase in the risk of unreasonable adverse effects on the environment that might result from approval of Rohm & Haas' applications; and

4) New information on the possible adverse effects of dicofol on the environment warrants reinitiation of consultation with OES concerning the impact of expanded dicofol use on threatened and endangered species."

Responding to these arguments, Petitioner points out that Respondent's refusal to grant conditional registration for Kelthane for at least six months has the effect of keeping these miticides off the market in 1987 for the first time in more than 30 years and jeopardizes their long-term viability as pesticides for controlling early season mites on

citrus in Florida and Texas and cotton in California (Petitioner's Reply at 2). It also points out that under the decision of May 29, 1986, Petitioner's products with more than 0.1 percent DDTr content may not be sold or used after December 31, 1988 (Id. at 10, 11). Petitioner asserts that the grounds cited by EPA for not granting the registration, i.e., the need to review data and consider the environmental risks of dicofol per se are not relevant to the conditional registration process and that these facts compel the conclusion that its registrations have been effectively denied.

Petitioner contends that the Agency cannot hide behind its own procedural failures to deny a hearing when refusing conditional registration under § 3(c)(6). It further argues that the only issues in this proceeding, that is whether the Agency can refuse conditional registration while it evaluates additional risk concerns about dicofol per se or assesses the environmental risks with and without Kelthane miticides on the market, are entirely legal questions. Petitioner emphasizes the Agency's conclusion at the termination of the Special Review that dicofol containing no more than 2.5 percent DDTr can meet the statutory standard for conditional registration and Respondent's concession (Tinsworth Affidavit) that Petitioner's products present no significantly different qualitative risk compared to currently registered products. Petitioner also notes that EPA's risk assessment procedures provide that the Agency is prepared to approve applications for identical and substantially similar products for new and amended registrations without individual risk assessments provided that other requirements for conditional registration are met (47 FR 57627). Rohm & Haas argues that the Agency cannot arbitrarily depart from its

established procedures in order to determine if Kelthane miticides will increase overall usage of dicofol. Moreover, it contends that such a departure would defeat the purpose of conditional registration and reintroduce the double standard which the enactment of § 3(c)(7) was designed to prevent (Reply at 8).

D I S C U S S I O N

Measured against the standards EPA has enunciated it will follow in considering and acting upon conditional registrations, there can be no escape from the conclusion that the Rohm & Haas application has been effectively denied. First, the Agency concedes that Petitioner's products present no significantly different qualitative risk compared to currently registered products (Tinsworth Affidavit). As indicated, note 6, supra, the Agency's policy is that granting additional registrations for pesticides identical or substantially similar to those currently registered will not increase overall usage of such pesticides, because the market for a particular pesticide is considered essentially finite. Moreover, the Agency has flatly stated (note 13, supra) that it will not require additional data in order to approve registrations of substantially similar products. Second, Mr. Tinsworth's letter to Rohm & Haas, dated January 27, 1987, indicates that the Agency will need a minimum of six months to decide whether to approve Petitioner's registration. His affidavit, however, pushes that schedule even further into the future, stating that the Agency may possibly be in a position to decide the registrability of Kelthane by the fall of 1987, but cautioning that the reviews

may be inconclusive and that additional data may be necessary. These facts, plus the Assistant Administrator's letter to Mr. Holcomb (note 8, supra), stating flatly that there will be no new registrations of products containing dicofol as an active ingredient until the Agency completes its review of pertinent data, compel the conclusion that Petitioner's application for the registration of Kelthane has been effectively denied.18/ It follows that Respondent's motion to dismiss this proceeding lacks merit and must be denied.

Having concluded that Petitioner's application has been denied, it should go without saying that the Agency may not rely on its failure to follow procedural steps required for a denial by § 3(c)(6) of the Act and regulation (40 CFR 162.7(f)), e.g., notification of denial and publication in the Federal Register, in order to deny Rohm & Haas a hearing. Any other conclusion would render the remedy envisaged by § 3(c)(6) of the Act illusory.19/

It is undisputed that Kelthane Technical complies with all of the requirements for conditional registration enunciated by the Agency at the conclusion of the Special Review in May of 1986 and with three of the four requirements for approval of requests for conditional registration set forth in 40 CFR § 162.167(a) (note 12, supra). It is also undisputed that Kelthane is substantially similar to registered dicofol products and

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18/ The regulation (40 CFR § 162.167(e)), note 14, supra), mandates a denial if there are insufficient data to make the required determination and under the Agency's view that it may need additional data to decide Petitioner's application, a denial is seemingly required, which, of course, would also entitle Rohm & Haas to a hearing.

19/ This is not to say that every case of delay in the determination of an application for registration will be equated with a denial, entitling the applicant to a hearing. Respondent concedes that this is an unusual situation (Transcript of Second Prehearing Conference, Tr. at 42) and the untoward effects on the registration program, which concerns Respondent (ante at 19), are unlikely to occur.

poses no significantly different qualitative risks. The only requirement at issue is that of § 162.167(a)(3) for a determination "[t]he use of the product will not cause a significant increase in the risk of unreasonable adverse effects on the environment."20/ Rohm & Haas contends that the undisputed facts referred to above plus the Agency pronouncements (notes 6 and 13, supra) as to how it would treat applications for substantially similar products proposing no new uses, mean that as a matter of law the Agency has made the required determination and that it is entitled to have its registration approved. Petitioner says that the need to study data and consider the environmental risks of dicofol per se are irrelevant to the conditional registration process as defined by the Agency. Otherwise stated, the goal of the conditional registration program, that substantially similar products be treated equally, requires that the Rohm & Haas registration be approved and that environmental concerns be addressed through registration standards, data call-ins, special reviews or other procedures, which, if warranted, effect current registrants as well.21/

20/ Respondent's argument (ante at 16) that the Act requires the Agency to make two separate determinations that approval of the application would not cause a significant increase in the risk of adverse effects on the environment, only one of which involves a comparison of the applicant's product with currently registered products, appears correct from the language of § 3(c)(7)(A), but has not been carried over to the regulation, 40 CFR § 162.167(a). See 47 FR 57626-27, December 27, 1982.

21/ The goal of the conditional registration program was equal treatment for like products. See Senate Report No. 334, 95th Congress, 1st Session (1977) at 108 "There has been general agreement among all interested groups, including the Administrator's Pesticide Policy Advisory Committee, that the double standard should be eliminated, and that like products should be treated in a like manner until reregistration subjects all products containing the same active ingredients to new requirements."

Respondent, on the other hand, contends that the incremental risk assessment it says it is conducting as to whether approval of Rohm & Haas' application would expand the use of dicofol is mandated by the Act.22/ It relies on a statement in Senate Report No. 334 (note 21, supra) at 10, referring to conditional registrations of "me-too" products and new uses of established pesticides and providing: "In each of these cases, the conditional registration would be granted only after a determination by the Administrator that the registration would not have unreasonably adverse effects on the environment and that there would be no major increase in the total amount of the material used." Respondent also quotes House Report No. 633, 95th Congress, 1st Session (1977) and an identical statement in the cited Senate Report at 20: "In most cases, conditional registration of products identical to those already on the market could be expected to have no significant environmental effect, but would simply alter the marketing structure with respect to the particular product."

Respondent alludes to the general rule that an agency may depart from an established policy provided it has a reasoned basis for doing so and asserts that here it has articulated compelling reasons for conducting an incremental risk assessment, even though its general policy is not to do so (Respondent's Reply at 6, 7). Respondent acknowledges, however, that Kelthane poses no significantly different qualitative risk than currently registered dicofol pesticides. The Agency has also acknowledged, in effect, that it does not at present have a valid basis for initiating

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22/ Respondent's Reply To Petitioner's Opposition To Respondent's Motion To Dismiss, dated March 23, 1987, at 4-6.

a new special review on dicofol in accordance with FIFRA § 3(c)(8) (Tr. 5, 6). The incremental risk assessment the Agency claims to be conducting appears then to be largely, if not solely, concerned with the alleged expansion in the use of dicofol that will result from granting of Petitioner's registration (Tr. 6, 7). This, of course, is precisely what the Agency has repeatedly said it will not do.23/

Rohm & Haas cites testimony of Agency official before Congress to refute what it regards as an isolated quote from the legislative history of § 3(c)(7)(A) upon which Respondent relies (ante at 25).24/ The mentioned quote from the Senate Report is seemingly at odds with the purpose of conditional registration and, if applied in every instance, would effectively negate the program. Moreover, as already demonstrated, the quote is flatly contrary to Agency pronouncements on conditional registration. It is therefore concluded that the quoted statement from the Senate Report does not support the Agency's action here, that is, conducting an incremental risk assessment, the primary purpose of which

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23/ In addition to the statements in the preamble to the regulations cited previously (notes 6 and 13, supra), see 47 FR 57626 "Until these risks [known and unknown] can be identified and addressed systematically through the registration standards process, and if necessary, the RPAR [now special review] procedure (see 40 CFR 162.11) little or no environmental protection is achieved by discriminating between products registered prior to 1975 and other prospective pesticide products."

24/ Petitioner's Reply at 33; Tr. 44, 45. Assistant Administrator Jellinek is quoted as stating "[W]e have stipulated, in essence, that we are not going to review data. We are going to assume that decisions made on existing pesticides were made correctly even though there are data gaps and even though we have not reviewed some of that data recently." Extension of Federal Insecticide, Fungicide and Rodenticide Act: Hearings on H.R. 7018 Before the Subcomm. on Department of Investigations, Oversight, and Research of the House Comm. on Agriculture, 96th Cong., 2d Sess. 95 (1980).

appears to be a determination of whether approving Petitioner's application would expand the use of dicofol, and reinitiating consultation with the OES, prior to acting upon Petitioner's application.25/ It should be emphasized that the Agency's apparent view that refusing Petitioner's application will limit the use of dicofol is tenuous indeed.26/

While the conditional registration program is discretionary, the Agency may not refuse or deny applications for conditional registration complying with 40 CFR § 162.167(a). As we have seen, the only one of the four requirements of § 162.167(a) in controversy is (a)(3), that is:

25/ I am aware that the Joint Explanatory Statement Of The Committee Of Conference on the Federal Pesticide Act of 1978, Commmittee On Agriculture, Nutrition and Forestry, U.S. Senate, 95th Congress, 2d Session (1979), provides at 20: "The conferees have agreed to the inclusion of new sections 3(c)(7)(A), (B) and (C) in FIFRA to authorize the Administrator to register pesticides conditionally on a case-by-case basis." The Agency has indicated, however, that only applications under 3(c)(7)(C), conditional registration of pesticides containing new active ingredients, will be handled on a case-by-case basis (47 FR 57626).

26/ A letter, dated March 23, 1987, from counsel for Makhteshim - Agan (America), Inc. (MAA) to Petitioner's counsel provides in pertinent part:

> As you are aware, the law of the United States establishes considerable restrictions on the sharing of information of the sort you request among competitors. We are authorized to state, however, that MAA is well aware of the size and significance of the United States dicofol market, and that the continued use of dicofol in other world markets is dependent, to a large extent on the continued vitality of the United States market. At this time, MAA is planning to allocate all of its product capacity over the coming months to the United States market. In addition, MAA is exploring ways to increase its dicofol capacity in the future. For example, MAA is giving most serious consideration to marketing in the United States, under MAA's label, technical material MAA would have obtained from Rohm & Haas, and expects to proceed to do so upon confirmation that product produced by Rohm & Haas meets the characteristics set forth in MAA's Confidential Statement of Formula, and upon completion of a mutually satisfactory commercial arrangement with Rohm & Haas, within the framework of regulatory requirements.

"[t]he use of the product will not cause a significant increase in the risk of unreasonable adverse effects on the environment." The Agency has set forth the requirements for continued registration of dicofol at the conclusion of the Special Review in May of 1986 and it is undisputed that Kelthane complies with those requirements. It is also undisputed that Kelthane is substantially similar to currently registered dicofol products and poses no significantly different qualitative risk. The Agency has acknowledged, in effect, that the new information it is considering does not, at present, provide a valid basis for reinitiating a special review. Under these circumstances, it is concluded that the required finding has been made, that the purported factual disputes set forth by Respondent, ante at 20, are not relevant to conditional registration[27/] and that Rohm & Haas is entitled as a matter of law to have its application for the registration of Kelthane approved.

Section 164.91 of the Rules of Practice (40 CFR § 164.91) provides in part that "[t]he ALJ in his discretion, may at any time render an accelerated decision in favor of Respondent as to all or any portion of the proceeding * *." While no background or history for this provision appears to be available, a reasonable conclusion is that it is designed only to preclude dismissal in Petitioner's favor without a hearing. So construed, the provision is not a bar to a decision in favor of Petitioner here, where no material facts appear to be in dispute and Petitioner is entitled to have its registration approved as a matter of law.

27/ Counsel for Rohm & Haas has stated that Rohm & Haas is requesting a hearing, not because it considers that there are any material facts in dispute, but because under the Act and regulations, that is its avenue for relief (Tr. 31).

Even if a hearing were considered necessary prior to a decision in Petitioner's favor, the two prehearing conferences might qualify as such.28/

O R D E R

Respondent's motion to dismiss is denied. Having been determined to comply with 40 CFR § 162.167(a), Petitioner's application for registration of Kelthane Technical29/ should be approved forthwith.30/

Dated this 24th day of March 1987.

Spencer T. Nissen
Administrative Law Judge

28/ Cf. Environmental Defense Fund, Inc. v. Costle, 631 F.2d 922 (D.C. Cir. 1980) (accelerated decision following prehearing conference and final order of Administrator on extensive documentary record held to constitute a public hearing within meaning of FIFRA § 16(b), thus conferring jurisdiction on Court of Appeals to review final order).

29/ While Rohm & Haas contends that the application for Kelthane MF is complete, there appears to be some confusion as to the precise status of the application (Tr. 3-5). Accordingly, this decision is limited to Kelthane Technical. It is assumed, of course, that after the registration of Kelthane Technical is approved, approval of other Kelthane registrations will follow.

30/ In accordance with 40 CFR § 164.91, this decision has the effect of an initial decision, which unless appealed in accordance with § 164.101 or, unless the Administrator orders review as therein provided, will become the final order of the Administrator in accordance with § 164.90(b).