UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of	)	
	)	
S.L. Cowley & Sons Mfg. Co., Inc.	)	FIFRA Docket No. 341
	)	
Registrant	)	

INITIAL DECISION

OF

EDWARD B. FINCH
ADMINISTRATIVE LAW JUDGE

By Notice of Intent to Cancel Registration, dated November 22, 1974, 39 F.R. 40980, and letter dated November 23, 1974, EPAX 1 GGG, S.L. Cowley & Sons Mfg. Co., Inc., was notified that it was the intention of the United States Environmental Protection Agency (EPA) to cancel registration of Cowley's Original Rat and Mouse Poison, EPA Reg. No. 505-1, for failure to meet efficacy requirements.

Upon the filing of objections and a request for hearing, EPAX 1 III, this proceeding was initiated. 40 CFR 164.20.

A prehearing conference was held on May 12, 1975, at which agreement was reached by counsel for informal exchange

of efficacy studies and other related matters. A further prehearing conference was held on December 22, 1975, and a report of that conference was issued on December 23, 1975.

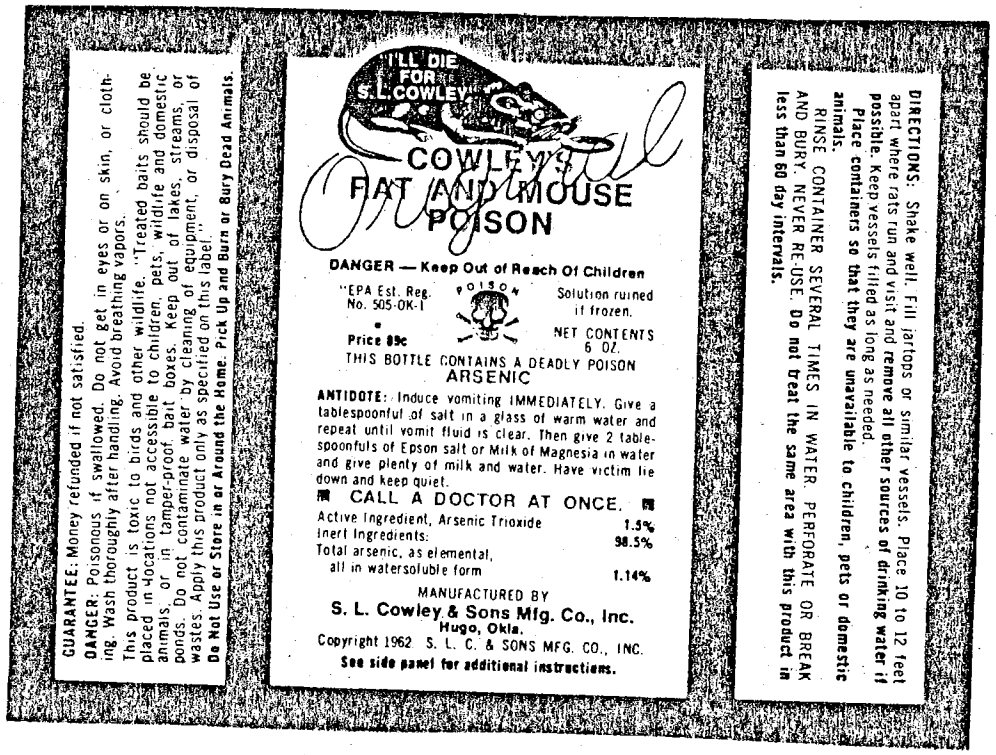
Hearings were held on January 27, 28, and 29, 1976 and on March 3, 1976, at which Registrant was represented by Michael S. Yaroschuk, Esq. and Respondent was represented by William A. White.

Briefs were filed by Registrant and Respondent on April 9, 1976 and replies on May 3, 1976.

Background

S. L. Cowley & Sons Manufacturing Company, Inc., is a small family business begun about forty years ago. The company at present consists of T.C. Cowley, his wife, and two helpers. The company has no regular sales force and engages in no advertising or other promotions. Essentially, its customers are regular repeat customers built up over the years. The product is manufactured almost on a per order basis; that is, during the busy season the product is run in small batches, usually enough to run for two to four weeks, and shipped directly to customers. At no time is a large inventory developed. During the year 1972 no more than 15,000 cases were produced and sold. The company's gross annual volume for 1971-1972 was approximately $45,000.

The manufacturing process is relatively simple. It consists of (1) a scale on which the ingredients are weighed and (2) a large 90-gallon pot in which the ingredients are mixed and thereafter bottled and shipped as ordered. A liquid, the product is offered as a water substitute. Cowley 20.



Label - Cowley 1

It is interesting to note the long history of negotiations and discussions between Registrant and the U.S. Department of Agriculture whose function herein was succeeded to by EPA.

Cowley's "Original" Rat and Mouse Poison was registered under Sec. 4 of the then Federal Insecticide, Fungicide, and Rodenticide Act on August 24, 1948, USDA Reg. 505-1. EPAX 1 H. Efficacy data for this type of product was not required in 1948, and none was submitted.

Registration for this product was renewed in October, 1953; February, 1959 and October, 1964. Again, efficacy data was not required and none was submitted.

It was not until February, 1966 that a label review of this product was undertaken and subsequently a bio-assay, both of which indicated some deficiency in the product, i.e., label content and lack of effectiveness under test conditions. By letter dated October 20, 1966, EPAX 1 I, Registrant was notified of these deficiencies and given 60 days in which to make label changes and provide studies to show that the product was efficacious.

Test Procedure and Results Thereof Set Forth in Letter of October 20, 1966

1. Twenty rats were individually caged.
2. White (albino) rats.
3. Treated and untreated water available. (Drinking font)
4. Position of water fonts changed daily.
5. First night five rats died.
6. No deaths after fourteen more days.

Correspondence regarding labeling continued to be exchanged until February 24, 1967 when Registrant advised USDA by letter, EPAX 1 M, that Bio-Assay Laboratory, Dallas, Texas, had been employed to conduct the studies requested by USDA.

Bio-Assay requested and was granted a six (6) month extension from March 6, 1967 to supply test study data.

Correspondence continued to flow until September 4, 1967, when, by letter, EPAX 1 Q, Bio-Assay Laboratory advised USDA that a 25% to 35% mortality was achieved in their studies of the efficacy of the product. At the same time, Bio-Assay requested a fifteen (15) month extension of time in which to formulate a new product or products to replace Cowley's arsenic trioxide rodenticide. This request was granted. EPAX 1 S and 1 T.

It should be borne in mind that during this period of time the instant product was being marketed and the registration was still in effect.

The parties continued to exchange letters re labeling and package size until March 25, 1968 when USDA wrote to Bio-Assay Laboratory, EPAX 1 AA, advising that "Since the product is marketed in 6-ounce containers to regular wholesale companies, we consider that it would move in channels of commerce where it

would likely be purchased by the homeowner. For this reason the product is not acceptable for continued registration." (Cowley's label stated the product was not to be used or stored in or around the home.)

During these negotiations USDA had issued an Interpretation No. 25 which was intended to restrict the use of certain products containing sodium arsenite and arsenic trioxide for use in and around the home. This Interpretation was not in effect on February 10, 1969, but when it became effective Cowley's product as then formulated, 1.75% arsenic trioxide, would be subject to cancellation, unless the arsenic trioxide content was reduced to 1.5%. See EPAX 1 C. Also see 40 CFR 162.123.

Interpretation No. 25 became effective on July 18, 1969. Under the Interpretation, all 1.75% arsenic trioxide liquid products packaged in containers less than one gallon were considered to be likely to result in their being purchased and used by the homeowner and, therefore, were not acceptable. As a result, by letter dated July 16, 1969, EPAX 1 DD, Registrant was advised that its registration would be canceled unless a hearing was requested or the product brought into compliance with Interpretation No. 25.

An Application for Amended Registration was filed by Registrant on August 11, 1969, EPAX 1 EE, which changed the formulation from 1.75% arsenic trioxide to 1.5%.

By letter dated September 8, 1969, EPAX 1 FF, another Notice of Cancellation was sent to Registrant, this time based upon the fact that the fifteen (15) month extension had expired and four (4) rodenticides had been registered by Cowley.

On October 10, 1969, Registrant objected to cancellation and requested a hearing. EPAX 1 HH.

By letter dated March 3, 1970, EPAX 1 JJ, USDA advised Registrant that since Application for Amended Registration of August 11, 1969 purports to bring the product into compliance with Interpretation No. 25, Notice of Cancellation dated September 8, 1969 was withdrawn. Since the record is silent on the matter, it is presumed that both Notices of Cancellation dated July 16, 1969 and September 8, 1969 were withdrawn by the March 3, 1970 letter of withdrawal.

By letter dated October 13, 1970, EPAX 1 KK, Registrant was advised that only the product containing 1.5% arsenic trioxide could be marketed.

By letter dated August 1, 1972, EPAX 1 OO, Registrant was advised separate samples of three shipments had been obtained and tested for percentage of arsenic trioxide content and for efficacy. In each instance the sample contained in excess of the stated percentage (1.5%) of arsenic trioxide and produced less than 90% mortality. Copies of charge sheets were attached. EPAX 1 LL; 1 MM; and 1 NN. Letter provided twenty (20) days for answer. Upon request the time was extended to October 15, 1972. EPAX 1 PP. Another request of October 2, 1972 for an extension of time to conduct tests was granted to January 15, 1973. EPAX 1 QQ.

Pursuant to request of January 10, 1973, EPA sent to Registrant a copy of a "suggested test procedure". EPAX 1 RR and attachment. Same as Cowley Exhibit 6.

Suggested Test Procedure

1. Remove all sources of drinking water except treated drinking water for 48 hours.
2. Use non-drip sipper tube.
3. Pen or tank and harborage suggested.
4. Ten female and ten male mice and albino rats.

5. Group caged.

6. Survivor observed for five (5) additional days.

7. Record deaths on day of occurrence.

8. Record bait consumption.

By letter dated January 15, 1973, Cowley 20, counsel for Registrant forwarded to EPA an explanation for overages in arsenic trioxide content mentioned in three (3) charges of misbranding and also copies of tests run by Mr. Harold Archey, a biologist employed by Registrant, to determine the efficacy of the product. Cowley 18 and 19.

Test Procedure Used By
Mr. Harold Archey

1. No drinking water available. Only test product.

2. Separate feed cups.

3. Pen or tank and harborage.

4. Five female and five male mice and Norway rats.

5. Individually caged.

6. All died in less than 24 hours.

7. Time of deaths recorded.

8. Bait consumption not recorded.

It should be noted that certain differences appear in the "suggested test method" and that used by Mr. Archey, i.e., feed cups were used instead of non-drip sipper tubes; five male and five female rats and mice were used instead of ten each; Norway rats were used instead of albino rats; and animals were individually caged instead of group caged.

However, by letter dated January 17, 1973, Cowley 21, Registrant suggested that these were only slight differences between actual tests run by Mr. Archey, Cowley 18 and 19, and the suggessted procedure forwarded by EPA on January 15, 1973, EPAX 1 RR. In reply, EPA, by letter dated February 22, 1973, EPAX 1 UU, disagreed and advised that the differences, such as lack of group caging, were significant. This letter also suggested additional testing.

By letter dated June 22, 1973, EPAX 1 LLL, Registrant submitted results of additional tests conducted on rats and mice in accordance with test procedures furnished by EPA. EPAX 1 SS, 3 Pages. Same as Cowley 7 and 8.

Test Procedures Used

1. All sources of untreated water were removed.
2. Used non-drip sipper tubes.
3. Pen or tank harborage as suggested.
4. Five female and five male mice and albino rats.

5. Group caged.

6. Recorded deaths every four hours.

7. Food consumed estimated for mice and not recorded for rats.

8. Test lasted 24 hours for mice and 6 hours for rats. Mortality was 100%.

Here the only difference was the use of five female and five male mice and albino rats instead of ten of each in each test.

By letter dated August 27, 1973, EPAX 1 KKK, EPA advised Registrant, "The test results submitted with your letter (June 22, 1973) have been reviewed and they were found to be acceptable according to present established standards and test protocol."

From this date until September, 1974, numerous letters were exchanged regarding destruction of labels, label changes, etc., but none related to test methods. Then, on November 23, 1974, a letter containing a "Notice of Intent to Cancel the Registration of Cowley's Original Rat and Mouse Poison, EPA Reg. No. 505-1," EPAX 1 GGG, was sent to Registrant. The basis for cancellation stated in the letter is as follows: "From May, 1966 to February, 1974 this product has failed to pass even one of twenty-three bio-assay efficacy tests against rats or mice. While Animal Biology Laboratory tests show that a single dose liquid rat and mouse oral rodenticide should produce a minimum of 90% mortality within 72 hours to be effective, this product has produced mortality ranging from 0% to 80% and averaging only 30.4%."

December 27, 1974 letter from counsel for Registrant to EPA, EPAX 1 III, objected and requested a hearing. January 23, 1975 letter from EPA to Registrant, EPAX 1 JJJ, advised Registrant to disregard the "Notice of Cancellation" pending the outcome of the hearing requested in letter of December 27, 1974.

Although I hesitated to burden this decision with the foregoing recitation of the chronology of events preceeding the hearing of this matter, I decided to include it since it serves to highlight the need for a more orderly and informed procedure in determining whether or not a registeration should be continued. In part, it is this pattern of events that compels me to reach the decision I have in this matter.

Respondent contends that the establishment of efficacy testing standards and procedure did not require informal rulemaking because, until its amendment in 1972, FIFRA was a self-implementing statute and such rulemaking as was necessary was accomplished through the formal process of notice and hearing. Although the FIFRA prior to 1972 had no provisions for setting standards in the registration of pesticides through regulations, it did provide that whenever it appeared to the Administrator that a particular registration did not conform to the provision of the Act, he must notify the registrant giving reasons for his actions, whereupon the registrant could request a formal hearing. When FIFRA was amended, in 1972, the

amended registration requirements did not become effective until regulations covering Section 3 of the Act were promulgated by the Administrator on July 3, 1975 to become effective August 4, 1975. 40 F.R. 28242. Until the regulations were promulgated, the provisions of FIFRA in effect on October 21, 1972 remained in effect. Federal Environmental Pesticide Control Act of 1972, Section 4, P. L. 92-516.

It is based upon the above and the fact that no regulations under Sec. 3 relating to guidelines or criteria for classification or registration were promulgated that Respondent contends the FIFRA prior to 1972 is self-implementing and that administrative due process is served by notice and hearing before an Administrative Law Judge.

Although some regulations for pesticide programs were published they did not concern guidelines or criteria for classification or registration.[1/] These were, however, published in the Federal Register in the form of proposed rules in accordance with procedures required by the Administrative Procedures Act.[2/]

Registrant contends that FIFRA prior to 1972 or after is not self-implementing and requires that any regulations which are to have the force and effect of law must be published in accordance with the procedures spelled out in the Administrative Procedures Act 5 U.S.C. 553 et seq. It would then seem necessary to discuss

1/ See generally 40 CFR 162.1-162.14.
2/ See p. 37 infra.

the validity, both technical and legal, of the test methods or protocols which were used to determine the efficacy of Cowley's Original Rat and Mouse Poison.

TECHNICAL VALIDITY

While test methods or protocols with variations have been used either by the U.S. Department of Agriculture or EPA since 1966, for the purposes of this decision only the methods described in EPAX C and D will be discussed, since Respondent alleges that these are the methods presently used and are the ones to which Cowley's product cannot conform. I will take official notice also of the test methods for rats and mice as they appear in 40 F.R. 26868, 26869, where they are designated "Exhibit 5--Proposed Acute Rat Liquid Bait Test Method," and "Exhibit 6--Proposed Acute Mouse Liquid Bait Test Method." These Federal Register documents, which appeared in "Guidelines for Registering Pesticides in United States," June 25, 1975, were not offered or admitted during the hearing. They were, however, referred to in Harrison Statement, p. 4, EPAX 1, and as appendices to Brief on Behalf of Respondent. These methods purport to be the same as EPAX C and D with language variations.

Respondent bases its contention as to the validity of these methods on the testimony of its experts, Mr. Herbert S. Harrison,

Chief, Insecticide and Rodenticide Branch, Registration Division, Office of Pesticide Programs, EPA; Mr. Paul M. Ochs, Criteria and Evaluation Division, Office of Pesticide Programs, EPA; Mr. John A. McCann, Supervisor, Animal Biology Laboratory, EPA and Mr. Steve D. Palmateer, Animal Biologoy Laboratory, EPA. Registrant bases its contention as to the invalidity of these methods on the testimony of its experts, Mr. Harold W. Archey and Dr. Allan J. Stanley.

Before discussing those points upon which there is disagreement, there are many facts upon which there is agreement by the parties, the primary one being that arsenic trioxide, the active ingredient in Cowley's product, is toxic and will kill a rat if a lethal dose is taken by the rat or is administered to the rat.[3/]

Commercial rodents (Norway rat, Roof rat, and House mouse) are difficult to control under actual use conditions for the following reasons, as summarized by Brooks, J.D. 1973. "A Review of Commensal Rodents and Their Control." Critical Reviews in Environmental Control, Vol. 3, pp 405-453, Appendix 6. EPAX 1 F.

Reproductive Potential

"Commensal rats and mice are characterized by rapid sexual maturation, short gestation periods, post-parturient estrus, polyestrous breeding, large litter

3/ A "pesticide" is defined in part as . . . "any substance or mixture of substances intended for preventing, destroying, or, mitigating any pest. . . ." 7 U.S.C. 136(u). Rodents are included under the definition of "pest" in the Act. 7 U.S.C. 136(t).

sizes, and short lives. These traits can result in exponential rates of population growth if food and cover are abundant." The high reproductive potential of commensal rodents is backed up by studies of the reproductive patterns of wild commensal rodents. The maximum number of viable offspring produced per pregnant female per year was 43 Norway rat offspring, 37 roof rat offspring, and 46 house mouse offspring.

Movements

Although daily movements of commensal rodents may only reach 30 feet for house mice and 150 feet for Norway and roof rats, ". . . seasonal changes in the environment may cause rats and mice to move considerable distances." Thus, even though a control program is successful in one area, movements of individuals into that area may necessitate a continuous control program.

Feeding Behavior and Habits

Rats are suspicious of any new article (including toxic baits) in their environment. The social habits of rats are a protection against poisoning of the general rat population. If there is an off-taste or if an illness is a result of what the rat eats or drinks, he will associate that with his food or drink and thereby cause the remaining population to shun that material. Rats require about 1/2 to 1 ounce of water a day when eating dry foods, less when eating moist foods.

Mice are nibblers. They will nibble from one food source and go to subsequent food sources, nibbling from each as they move. This means that it is difficult to get the mouse to consume enough toxicant to cause mortality. Mice normally consume 3/10-ounce of water but can survive on 3/100-ounce. More recent studies have shown that house mice can survive for months without water when fed a diet of seed. . . .

Competition Among Individuals In A Population

As rodent populations increase in size, competition among its members for limited food, water, and living space increase. As the capacity of the environment (limitations of food, water, and space) is approached, population growth slows down and reaches an equilibrium. This slowing down and leveling off of population numbers is accomplished mainly through the increased competition, which leads to increased aggression, increased mortality, decreased births, and increased dispersal. The end result is that limiting factors such as food and water are not exhausted.

Conclusion

Because of the above difficulties associated with controlling rats and mice under actual use situations, toxicants (including acute single-dose liquids) should be as efficacious as possible.

Controlling rats and mice is usually easier under laboratory conditions than under actual use conditions for the following reasons.

Access to the Toxicant

Under laboratory conditions all animals have access to the bait. Under actual use conditions, some animals may not have access to the toxicant because of environmental complexity, rodent behavior, and user skill in bait placement.

Weather

In contrast to laboratory conditions, the weather under actual use conditions may make the toxicant less effective.

Interference With Bait Placements

In contrast to laboratory conditions, children and non-target animals may interfere with the control programs by removing, spilling, fouling, or drinking the liquid toxicants.

Alternate Sources of Water

While laboratory conditions provide animals with only one alternate source of water, actual use situations may provide animals with one or more alternate sources of water. As mentioned above, because of competition among individuals, wild rat and mouse populations tend to reach an equilibrium level before they exhaust food, water, and space. Therefore,

> where rats and mice are a problem, there are usually alternate sources of water to compete with any liquid toxicant. And even if there are not, rats are able to obtain their water requirements from garbage, and mice are able to obtain theirs from certain food like seeds. Since laboratory test conditions usually do not duplicate the often severe problems encountered in actual use situations, laboratory tests will often overestimate the efficacy of a product under actual use conditions.

Registrant contended that laboratory tests will not indicate the efficacy of the product since rats in different environments will act differently. Dr. Stanley stated that a different method for each different environment must be devised. TR p. IV 57-9. Further, laboratory tests are not scientific or sound nor can laboratory results be extrapolated to field results. Dr. Stanley stated, "my only purpose in coming here is to say that all experimentation that's been done on the laboratory rat is of no value in my judgment on the assessing of the efficacy of any kind of drug, medicine, or poison in a wild rat population." TR. p. IV 42-21. Dr. Stanley further testified that it is not necessary to achieve a 90% mortality of rats in a test to insure a high percentage of mortality in the field. He states that a 30% kill on a frequent basis would be a control. It was conceded by both parties that it is virtually impossible to eradicate a rat population and, therefore, we are only concerned here with the control of rat populations.

A statement in a paper by Curt P. Richter which was referred to frequently during the hearing reads as follows:

> "There can be little doubt that poisoning or trapping of a block or any confined area is useless without a follow-up--a search for signs of surviving rats and further treatment with poison or traps--aimed to get rid of the last rat. This may require time and effort, but both are well spent, because blocks treated in this way may remain rat-free for years. Elimination of only 60-80 per cent of rats is in my opinion useless."

It has been implied that this statement supports justification for the 90% mortality rule set forth in the test method. In fact, Mr. Palmateer, a witness for EPA, testified that "No author has said verbatim that a 90% mortality in the laboratory is going to insure a good kill in the field. TR. p. IV 123-17. Dr. Stanley asserted that the Richter statement does not call for a 90% mortality rule. He stated that "to kill 60% to 80% is useless", does not mean that the percent of efficacy must be higher than that but rather that if you kill 60% to 80% and then forget your control program, then it would be useless. Even Richter noted that follow-up is necessary. Dr. Stanley also noted that a 30% to 50% mortality would be sufficient on a continuing basis to control rat population. TR. p. IV-58.

The test methods were generally criticized on additional bases, as well. For example, Dr. Stanley testified that the only way to measure the effectiveness of a rodenticide is to administer it by use of a tube or needle. TR. p. IV 50-2.

Registrant stated that in a laboratory test, individual caging of the animals is preferable to group caging. Respondent contended, however, that individual caging does not simulate the natural environment and for that reason group caging is used by EPA. Finally, Registrant stated that Norway rats, which are the target animals, should be used instead of albino rats. The test method calls for either.

Registrant also offered specific criticisms pertaining to the testing of its own product. Registrant stated there should be no alternate source of water for 48 hours. The label on Cowley's product states "remove all other sources of water if possible." Respondent noted that it is impossible to remove all sources of water in the natural habitat and, therefore, that the test method should include such alternate source from the beginning of the test.

One of the difficult questions here involves the applicability of the language of the test method to the language on the label. Registrant contends that the product should be tested using the instructions on the label which prescribe that all other sources of drinking water should be removed if possible. Registrant's tests show the product to be 100% effective and acceptable when these instructions are followed in laboratory testing. EPAX 1 SS, 1 LLL, and 1 KKK.

A factor which makes this problem more difficult to evaluate is that all test methods which have been made a part of this record contain language such as the following:

> "It (the method) is designed to determine effectiveness of acute liquid rodenticides applied according to instructions on the label. (Emphasis supplied.) 40 FR 26868.

And,

> "Fill half the waterers with tap water and the other half with test liquid bait formulation diluted with tap water according to use directions. (Emphasis supplied.) EPAX 1 C.

And yet, Respondent contends that it is impossible to eliminate all alternative drinking water or water sources from the natural environment of the rat or mouse and for that reason and, that reason alone, asserts that when EPA tests an acute liquid rodenticide, it will depart from its own proposed test method, i.e., ignore the "instructions for use on the label" of the product and supply an alternate source of water in the laboratory test method. TR. 1-200. Further justification for this departure is supplied by Respondent in that it alleges Cowley's Rat & Mouse Poison fails the 90% mortality test in its tests under either condition. TR. p. 3-89-90.

It would seem that the proper procedure for Respondent to follow would be one of two courses of action:

1. Disapprove labels which require removal of water sources when it can be shown that this is impossible in field conditions, and should not be simulated in laboratory tests; OR

2. Establish another test method which eliminates the requirement that the test is to be conducted according to instructions on the label.

It is a basic rule of administrative law that an agency is bound by its own rules. See Oil Shale Corp. v. Morton, 370 F.Supp. 108, 122 (1973); McKay v. Wahlenmaier, 226 F.2d 35, 43 (1955).

Registrant contends that old FIFRA is strictly a labeling statute and since the word "efficacy" is not used therein, the action of EPA in testing for efficacy under that statute is invalid. I reject this contention. While it may be true that the Act is not specific in this regard, such authority must be implied from the requirements set forth therein even if only from the general authority to approve labels.

I must also reject the contention of Respondent that the preliminary action taken by the American Society for Testing and Materials with regard to the approval and publication of the test methods or protocols used by EPA should be considered as giving some validity to these methods.

It is not unusual for a Federal agency to invoke a test method or protocol in a proceeding involving quantitative or qualitative analysis where such test method has been accepted by the affected industry and has, in fact, been published in recognized periodicals or books by recognized organizations such as the American Society for Testing and Materials. This is true of proceedings held by the Federal Trade Commission under the Wool Products Labeling Act,

the Fur Products Labeling Act, and the Textile Fiber Products Identification Act. The FTC has not issued rules (test methods or protocols) for the qualitative or quantitative testing of textiles and furs, but has relied for enforcement purposes, upon recognized published test methods accepted and used by the regulated industry. F.T.C. v. B. Wollman & Sons, Inc.; Docket No. 8540, 63 F.T.C. 1617 (1963); F.T.C. v. R.H. Macy & Co., Inc., Docket No. 8650; 72 F.T.C. 894-896 (1966) and 72 F.T.C. 947 (1967).

However, here the record is replete with statements to the effect that no authority on the control of rats, and the record names almost 25 such experts, has ever put in writing a percent of mortality required to declare a single dose acute rodenticide to be efficacious or inefficacious.

I do not in any way question the expertise of the EPA witnesses who subscribe to the 90% laboratory mortality figure and their basis for it seems reasonable, but neither do I question Dr. Stanley's statement that it is not necessary to achieve a 90% laboratory mortality figure to be effective. The statements of the witnesses are the sole source upon which a determination can be made as to the appropriateness of the 90% mortality rate in the efficacy test method procedure.

I find that it is essential for the administration of FIFRA for the EPA to establish test methods or protocols for use in a laboratory to determine the efficacy of products subject to registration either under FIFRA prior to 1972, and the 1972 version. However,

there is not sufficient evidence in this record upon which a finding can be made that the subject test methods or protocols are technically and validly based. More is required, and the procedural requirements of the APA would accomplish this. In any event, such procedures would tend to dispel any future objections in a similar action to cancel a registration.

LEGAL VALIDITY (PROCEDURAL REQUIREMENTS)

The EPA, as an agency of the United States Government, is subject to the provisions of the Administrative Procedures Act (APA, 5 U.S.C. § 500 et seq. (1967). Section 551 of the APA provides that for the purposes of the Act

> ". . . [A]gency means each authority of the Government of the United States, whether or not it is within or subject to review by another agency . . . ."

The APA establishes procedural requirements for three occasionally overlapping administrative functions: individual adjudication, adjudicatory-type rulemaking, and informal rulemaking. 5 U.S.C. §§ 553, 554 (1967).

EPA asserts that FIFRA prior to 1972 was self-implementing and that administrative due process was served merely by the giving of notice to a party that an action against it is being initiated and the subsequent hearing wherein all facts are argued before an Administrative Law Judge. Consequently, APA rulemaking procedures may, according to Respondent, be by-passed in this instance.

Registrant asserts that the action of the Administrator in attempting to enforce the subject test methods or protocols constituted informal rulemaking. Therefore, since the Administrator did not comply with the requirement of the APA that he permit public participation and accept data and other comments from interested parties, the Notice of Intent to Cancel the registration of Cowley's Original Rat and Mouse Poison should be vacated. I agree.

Section 553 of the APA provides in part:

> "Rule making
>
> . . . . . .
>
> (c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose." (5 U.S.C. § 553 (1967))

Thus, as a general proposition, administrative rulemaking must permit some public participation in the decision-making, and in a generalized way, it must articulate its bases and purpose.

The distinction between individual adjudication and rulemaking can become blurred in borderline cases. Administrative adjudication is concerned with the determination of past and present rights and liabilities of parties. Rulemaking, on the other hand, involves the prescription of law to effect broad policy considerations. See American Airlines Co. v. Civil Aeronautics Bd., 123 U.S. App. D.C. 310. 359 F.2d 624, 629 (1966). While rulemaking always affects individual rights and liabilities in some measure, a line must be drawn at some point.

An agency is not adjudicating when it is formulating a test method or protocol to fit future cases. A test method, as here, is designed to fit all cases at all times. It is not particularized to special facts. It is, in effect, a statement of far-reaching policy covering all future efficacy tests for single-dose acute rodenticides.

It is clear that EPA has both rulemaking and adjudicatory powers. However, "adjudication" is defined in the APA as agency process for the formulation of an order, and "order" is defined as "the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rulemaking. . . ."

I do not agree with EPA that the instant matter is one that falls within the informed discretion of the Agency, i.e., to proceed either by rulemaking or adjudication. It is certainly proper for EPA to proceed by adjudication to cancel a registration which is by way of a final order, but the broader concept of whether the basis (protocols) for such cancellation is proper, is one which involves the strict rule-making procedures required by the APA.

EPA relies upon S.E.C. v. Chenery Corporation, 332 U.S. 194, 67 S.Ct. 1575 (1947) for the rule that the choice between proceeding by general rule or by individual, ad hoc litigation lies primarily within the informed discretion of the administrative agency.

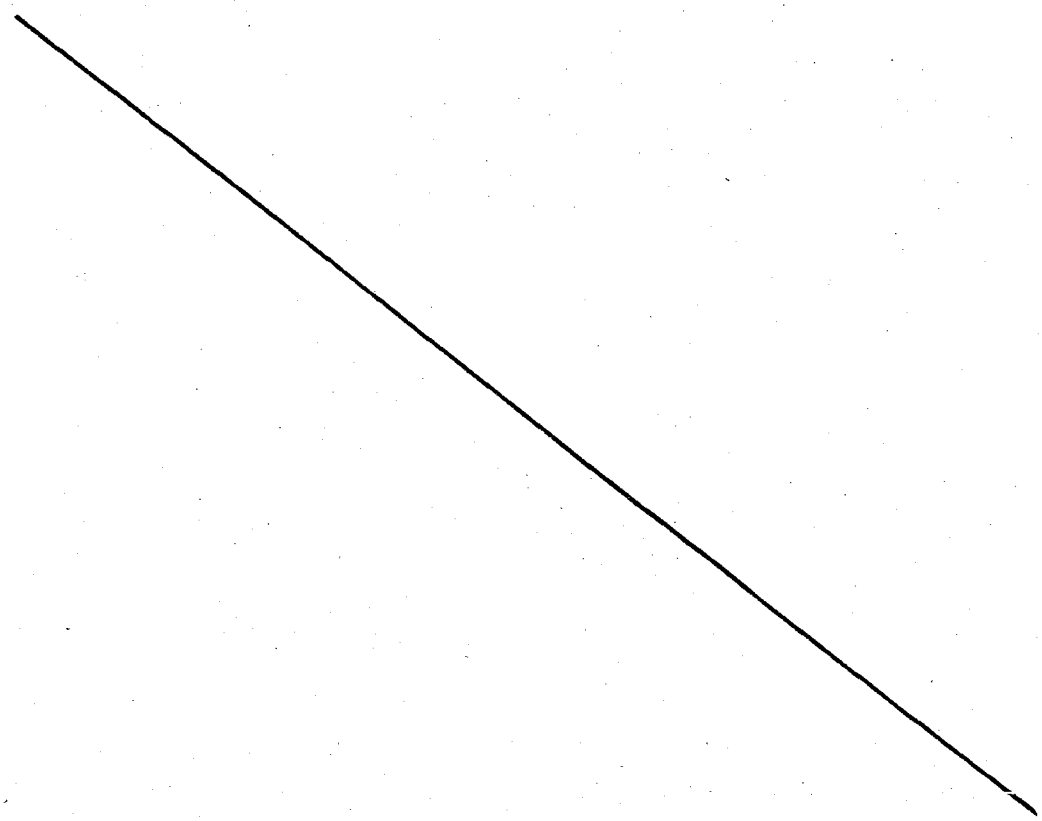
However, the basis for that rule as in relation to the facts of the instant matter is readily distinguishable. In Chenery the court stated:

> "In other words, problems may arise in a case which the administrative agency could not reasonably foresee, problems which must be solved despite the absence of a relevant general rule. Or the agency may not have had sufficient experience with a particular problem to warrant rigidifying its tentative judgment into a hard and fast rule. Or, the problem may be so specialized and varying in nature as to be impossible of capture within the boundaries of a general rule. In those situations, the agency must retain power to deal with the problems on a case-to-case basis if the administrative process is to be effective. There is thus a very definite place for the case-by-case evolution of statutory standards."

This situation does not exist here. The fact that EPA has proposed test methods or protocols in the Federal Register negates a justification based on Chenery, for selecting adjudication in this case. In fact, the record discloses that as early as

1973 test methods or protocols similar to those which appeared in the Federal Register were published and in effect in EPA Technical Services Manual. TR. p. IV-166. I have no difficulty in finding that the establishment of a test method or protocol to determine efficacy of a product for registration purposes falls on the rule-making side of the line even though individual rights will at some time in the future be affected.

I further find that the determination as to the reasonableness and appropriateness of the test methods or protocols which were discussed at length in this proceeding does not fall within the definition of "adjudication" and "order" mentioned above.



In Buckeye Power, Inc. v. EPA, 481 F.2d 162 (1973), where public utilities filed petitions for review of action of the Administrator of EPA in approving state plans for implementation of ambient air quality standards and the court deferred approval of the plans until the Administrator complies with Section 553 of the APA, the court referred to a proceeding wherein the Supreme Court, in Citizens To Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971), explained why these basic requirements for administrative rule-making are necessary, stating that without permitting public participation and without developing the record, the administrative agencies would nullify the federal courts' function of administrative review.

The Court stated:

> "Scrutinizing of the facts does not end with the determination that the Secretary has acted within the scope of his statutory authority. Sec. 706(2)(A) requires a finding that the actual choice made was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. Sec. 706(2)(A)(1964 Ed. Supp. V.. To make this finding the court must consider whether the decision was based on a consideration of the relevant factors and/or whether there has been a clear error in judgment." (401 U.S. at 416.)

It has been recognized consistently that without informed judicial review of agency actions, ". . . expertise, the strength of modern government, can become a monster which rules with no practical limits on its discretion." New York v. United States,

342 U.S. 882, 884, 72 S.Ct. 152, 153, 96 L.Ed. 662 (1951) (dissenting opinion), quoted in Burlington Truck Lines v. United States, 371 U.S. 156, 167, 83 S.Ct. 239, 9 L.Ed 2d 207 (1962).

The Administrator built no record in approving or disapproving the state plans. He took no comments, data, or other evidence from interested parties, nor did he articulate the basis for his actions. This failure contravenes the explicit dictates of Section 553 of the APA and renders meaningless the judicial review provisions of Section 706. (481 F.2d at 171.)

With those basic tenets in mind, I will proceed to discuss the leading cases in point. I rely on N.L.R.B. v. Wyman-Gordon Company, 394 U.S. 759, 89 S.Ct. 1426 and its discussion of the Excelsior rule in which the Board purported to establish the general rule that an employee list must be provided to unions where an election is to be held, 15 N.L.R.B. 1236 (1966). The Board held that the list was to be provided to the union, but held the rule would apply "only in those elections that are directed, or consented to, subsequent to 30 days from the date of the decision." The Supreme Court, by plurality vote, although affirming the action of the Board for other reasons, held in Wyman-Gordon that the Excelsior rule was invalid in that the required procedures of the APA were not followed.

If the Board in the "Excelsior Rule" case had drafted the Order to require the giving of the list of employees applicable

to the parties to that proceeding instead of making it applicable only in elections subsequent to 30 days from the date of the decision, the Supreme Court may have held that the Board acted within its adjudicatory authority, that the Order was within the definition of "adjudication" and "order" as defined in the APA. The decision would then be considered administrative stare decisis as was suggested by the plurality opinion. See Wyman-Gordon, supra, at 1429.

The order under review in Wyman-Gordon was simple, i.e., the company must supply a list of its employees to the union. There were no other factors to be considered. In the instant matter the order to be considered is whether or not registration should be cancelled for Cowley's product. This is adjudication pure and simple. However, before a decision can be rendered on this point, another factor must be resolved, i.e., whether the test method or protocol upon which this decision will be based is a reasonable and proper test, which is also valid in law. Therefore, even if the dissent in Wyman-Gordon which held that the Excelsior Rule was proper adjudication, were the plurality opinion, I distinguish the two cases on issues presented.

As I find in the instant case, the Wyman-Gordon court was of the opinion that the "rule" in dispute was substantive and that it therefore does not fall within any of the exceptions. See 5 U.S.C. Sec. 553(b)(A).

It should be pointed out that EPA cites no authority for a statute being "self-implementing" as is claimed here. That argument is further vitiated by the fact that the APA was enacted and in effect during the entire period of negotiations between the parties to this proceeding and is applicable to actions under FIFRA both before and after the 1972 amendment.

Another leading case in point is Pharmaceutical Manufacturers Association v. Finch, 307 F.Supp. 858 (D.C. Del. 1970) wherein plaintiffs argued that certain proposed regulations were "invalid" because they were issued without notice and opportunity for comment in violation of the requirements of Section 4 of the APA. In that case the court made a statement which is on all fours with the facts of the instant case (307 F.Supp. at p. 864):

> "The September regulations, which prescribe in specific detail, for the first time, the kinds of clinical investigations that will be deemed necessary to establish the effectiveness of existing and future drug products and which require that such evidence be submitted as a condition to avoiding summary removal from the market, are pervasive in their scope and have an immediate and substantial impact on the way PMA's members subject to FDA regulation, conduct their everyday business. The regulations apply to more than 2000 drug products first marketed between 1938 and 1962 with FDA approval and place all of them in jeopardy, subject to summary removal by order of FDA.
>
> "The all pervasive and substantial impact which the September regulations have upon the drug industry and in turn upon prescribing physicians and their patients, makes it imperative that the Commissioner comply with the notice and comment provisions of Section 4 before such regulations become effective."

Although the Commissioner argued the regulations were "procedural and interpretive," the preliminary injunction was granted.

Similarly in the case of Clever Idea Co., Inc. v. Consumer Product Safety Commission, 385 F.Supp. 688 (1974), where manufacturers sought a preliminary injunction restraining CPSC from enforcing regulations banning distribution of toys which utilized plastic mouthpieces on the ground that the "bite" test regulation had only been proposed but not promulgated or adopted, the court in granting the preliminary injunction relied upon Pharmaceutical Mfrs. Association, supra, again stressing the point that the regulations place all of plaintiffs' mouthpieces in jeopardy, subject to summary removal by order of the Commission. And further:

> "Again "the all pervasive and substantial impact which the (proposed Regulations have upon plaintiffs') industry * * * make it imperative that the (Commission) comply with the notice and comment provisions of Section 4 (5 USC § 553) before such Regulations become effective."

I, of course, recognize that in Clever Idea Co., Inc., the APA procedures were mandated by the organic statute. I repeat, however, that under the Chenery rule and its related facts no discretion would be permitted in this case.

A series of cases involving a holding that APA compliance is a prerequisite to enforceability are many and varied. See, e.g., National Motor Freight Traffic Assn. v. United States, 268 F.Supp. 90 (1967), aff'd per curiam, 393 U.S. 18, 89 S.Ct. 49 (1968);

action by ICC in establishing an informal procedure for restoration to shippers of past charges which are currently agreed to be illegal; Detroit Edison Company v. E.P.A., 496 F.2d 244 (1974), petition for review of an order approving amendment of Agency's regulation, which required that owner and operator of stationary source comply with provision of state plan pertaining to emissions. Agency approval of change in regulation was substantial and required APA procedures. Wagner Electric Corp. v. Volpe, 466 F.2d 1013 (1972), right of interested person to petition for a change in a rule is neither a substitute for nor an alternative to compliance with mandatory pre-rulemaking notice requirement of the APA; Texaco, Inc. v. F.P.C., 412 F.2d 740, (1969), gas company not given required notice concerning rule to compound interest rates; Hotch v. United States, 212 F.2d 280 (1954), a regulatory extension of statutory closing hours for fishing; Nader v. Butterfield, 373 F.Supp. 1175 (1974), internal memorandum viewed as an "instructive communication" to FAA employees re X-ray devices does not dispense with APA requirements; Kelly v. U.S. Dept. of Interior, 339 F.Supp. 1095 (1972), good cause requirement for not following APA must be preceded by a finding that compliance with 30-day requirement is impractical, unnecessary or contrary to the public interest; Seaboard Air Lines v. Grounouski, 230 F.Supp. 44 (1964), policy directive pertaining to transportation of overseas air mail.

Respondent has cited in its brief the matter of Bird-X Petrogel Bird Repellent, I.F. & R. Docket No. 241 (1973) to advance the proposition that prior to the publication of formal regulations standardizing registration procedures such rule-making as did occur was the result of the cancellation hearing process. And that in that case, as well as 707 Company, FIFRA Docket No. 301, the standard and procedures developed by EPA are central to the issues of the case.

In Bird-X, registrant was requested by the Administrator of EPA to submit a full description of tests made, and the results thereof, upon which the claims of efficacy were based, but such tests were not conducted by or on behalf of registrant and the registration was therefore cancelled.

The instant matter is distinguishable in that the registrant did conduct tests and submit results, some of which prompted EPA to write a letter to Cowley approving test methods and test results. EPAX 1-KKK.

In 707 Company, it is true that a test method or protocol was contested. However, I distinguish that case from the instant case due to the fact that the questions here presented relating to "adjudication" as opposed to "rule-making" were not at issue there.

While EPA is asserting on the one hand that the Act is self-implementing, actions by the U.S. Department of Agriculture and its successor to the administration of this Act, the EPA, give another view. The present regulations which appear in 40 CFR 162 et. seq., were published in accordance with the requirements of the APA. See F.R. Doc. 63-9541, Sept. 6, 1963 and F.R. Doc. 64-392, Jan. 16, 1964.

The test methods or protocols which are the subject of this proceeding are being finalized in accordance with the requirements of the APA in the form of guidelines.

These Guidelines were published in the Federal Register on June 25, 1975, as proposed rules. 40 F.R. 26802. Public comment was invited, the comment to be received on or before August 27, 1975. These Guidelines will appear in the Code of Federal Regulations at 40 CFR 162.40 through 162.96 when finalized.

A section of the Guidelines is entitled Rodenticides--Acute and Chronic. 40 F.R. 26866, a portion of which deals with the efficacy thereof and reads:

> "Laboratory Methods. The Environmental Protection Agency has developed methods that have been used for establishing laboratory efficacy of rodenticides for commensal rodents. (See Exhibits 1-8.)"

Exhibits 1, 2, 3, 4, 7, and 8 refer to test methods for anticoagulant liquid and dry rat and mouse baits and acute rat and mouse dry baits. Exhibit 5 is a Proposed Acute Rat Liquid Bait Test Method which was prepared by the Technical Services Division, OPP, EPA. The format follows the style requirements of the American Society for Testing and Materials. 40 F.R. 26868. See also EPAX 1 G, with variations. Exhibit 6 is a Proposed Acute Mouse Liquid Bait Test Method which was prepared by the Technical Services Division, OPP, EPA. The format follows the style requirements of the American Society for Testing and Materials. 40 CFR 26869. See also EPAX 1 D, with variations.

The following are excerpts from the preamble to the proposed Guidelines which it seems are appropriate to refer to in dealing with the problem of the validity in law, or the present legal status of any rodenticide test method now being used for registration or enforcement purposes.

Legal Status

> "Section 3(c)(2) of the FIFRA provides that the "Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time." Furthermore, Agency is required to follow the provisions of the Administrative Procedure Act (APA). The APA (5 U.S.C. et. seq.) defines "rule" to mean:
>
> * * * the whole or part of an agency statement of general or particular applicability of future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure or practice requirements of an agency. * * * "
>
> "The issuance of the Guidelines is an implementation of the amended FIFRA, and, therefore, under this definition, constitutes rulemaking. The APA establishes two types of rulemaking procedures: "informal" and "formal" or adjudicatory rulemaking. Formal rulemaking procedures

generally are required when the statute concerned expressly requires that rulemaking be conducted "on the record." FIFRA imposes no such requirements: therefore, informal rulemaking procedures are applicable to the Guidelines.

"The Guidelines are to be used in conjunction with Title 40, Code of Federal Regulations, Part 162, Regulations for the Registration, Reregistration and Classification of Pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act.

Purpose

"The overall purpose of the Guidelines is to inform interested members of the general public of the factors entering into the pesticide registration process, to encourage and enhance the ability of the applicant for registration to present an adequate and completely documented application, and to assist the Agency in expediting the review procedure. Such guidance will reduce some of the uncertainty associated with achieving compliance with the requirements for registration. The Agency believes that the decisions, allowing for the range of variables involved in pesticide Guidelines as proposed will apply to the vast majority of registration decisions, allowing for the range of variables involved in pesticide registration.

"If an applicant questions the applicability of the Guidelines to his own situation, he may propose for approval an alternative approach better suited

to his case. The Guidelines therefore are designed to serve the public interest without establishing requirements which are inflexible or inappropriate to particular registration actions.

Appendices to Guidelines

"The significance and validity of information required by the Guidelines depend on the test procedures employed to develop it. Thus, the Guidelines are accompanied by the Appendices describing test procedures which have been determined to be adequate to provide data satisfying registration in the majority of cases. Such a comprehensive step has not been taken in the past with respect to Federal regulation of pesticides. The Appendices describe those test methods, procedures, or protocols related to developing registration data for: (1) Product efficacy. . . . Because of the diversity of the materials, the information is presented in several formats. . . .

(3) Full text (with source credit) of unpublished methods or protocols of those that are not readily available . . . .

"The Appendices contain examples of test procedures that are acceptable to the Agency. However, the Agency recognizes that applicants may be aware of other test procedures which are equally effective for particular purposes and that new procedures will be developed in the future. It also recognizes that the test methods described in the Appendices sometimes may not be well suited to the evaluation of certain products. Therefore, applicants for registration may be permitted to use

> procedures other than those set out in the Appendices, provided that the new methods do not detract from the intent and reliability of the Guidelines/ Appendices. Similarly, applicants may be sometimes required to use other procedures if the protocols in the Appendices are not applicable. In all cases, the burden is on the applicant to exercise his best scientific judgment." See also TR 1-187.

It is, therefore, obvious that, at least with regard to the 1972 amendment, the Agency itself considers APA applicable and such test methods are not enforceable until finalized.

Further excerpt from the preamble to the proposed Guidelines; June 25, 1975, 40 F.R. 26804.

Means of Issuance

> The Guidelines and Appendices will be published in the Federal Register in final form with such changes as the Agency deems warranted upon consideration of all comments. . . .
>
> The Guidelines and Appendices are not intended to be static. As new material is developed, the existing documents will be expanded and modified. Any major change will be made in accordance with the informal rulemaking procedures of the APA. Changes to the Guidelines and Appendices which are routine or insignificant in nature or impact, and therefore unimportant to the industry and the public will be adopted without prior notice and opportunity to comment, pursuant to the provisions of the APA authorizing such procedures where the Agency finds that notice and comment are either impracticable, unnecessary, or contrary to the public interest.

All of Respondent's witnesses readily admit that since the inception of the need for a test method to determine the efficacy of rodenticides, there have periodically been changes made as deemed necessary and it was not until late 1974 or January, 1975 that the present proposed test method was decided upon. And that, in fact, Registrant was provided with test methods with varying requirements during the period 1966 to November, 1974 when the intent to cancel was issued.

It is, therefore, apparent that the U.S. Department of Agriculture and EPA in time periods both prior to and after the institution of the instant proceeding were aware of and in fact did comply with the informal rule-making requirements of the APA.

In spite of the good intentions of EPA to move into the area of enforcement armed with only "note-book" laboratory test methods, I must find that those "note-book" laboratory test methods and the proposed test methods contained in the Guidelines are not enforceable in law since they have not been finalized and made effective through the procedures required by the Administrative Procedures Act. 5 U.S.C. 553, et seq.

FINDINGS OF FACT

1. It is reasonable and proper for EPA to establish test methods or protocols for determining the efficacy of single-dose acute rodenticides.
2. Such tests are necessary to the proper administration of FIFRA.
3. It is essential that these test methods or protocols be established on the basis of laboratory techniques which simulate field conditions.
4. These test methods or protocols must be established and promulgated under the informal rule-making requirements of the Administrative Procedures Act 5 U.S.C. 553 et seq.
5. Procedures are presently being utilized by EPA to establish test methods or protocols for acute rat liquid bait in compliance with the APA.
6. The test methods or protocols which form the basis for the intent to cancel the registration of Registrant's product were not established under the informal rule-making requirements of APA and are, therefore, invalid and unenforceable.

CONCLUSION

I am fully aware that Sec. 164.80 requires that the ultimate burden of persuasion shall rest with the Registrant on all issues arising in connection with the hearing. The intended issue here concerns the efficacy of Registrant's product. I conclude, however, that Sec. 164.80 is inapplicable in this matter due to the fact that this burden of persuasion applies only where a rule, valid in law, is being applied. Since I have found that the rule (test method or protocol) is not valid in law;

IT IS ORDERED that the Notice of Intent to Cancel Registration of Cowley's Original Rat and Mouse Poison, EPA Reg. No. 505-1, for failure to meet efficacy requirements, is hereby vacated.

Edward B. Finch
Administrative Law Judge

May 28, 1976

NOTE: Pursuant to Section 164.90(b) of the Rules, this initial decision shall become the decision of the Administrator without further proceedings unless an appeal is taken within 20 days by the filing of exceptions pursuant to Section 164.101(a) of the rules, or the Administrator orders review pursuant to Section 101(b).