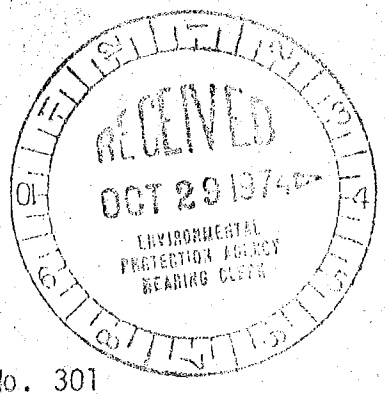

ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of	:	
The 707 Company	:	FIFRA Docket No. 301
Registrant	:	

INITIAL DECISION
Of
Frederick W. Denniston
Administrative Law Judge

By Notice of Intent to Cancel Registration, dated December 28, 1973 (39 F.R. 1665), proposed to cancel Registrant 707-Warfarin Mouse and Rat Killer, EPA Registration No. 1193-48 and 707-X Kills-Controls Rats-Mice, EPA Registration No. 1193-17, in both instances for the reason that: Failure to submit efficacy data; failure to submit corrected, finished labels. The Notice was served on the Registrant on January 16, 1974. Upon the filing of Objections and Request for Hearing, this proceeding was instituted (40 CFR 164.20).

A prehearing conference was held on May 20, 1974, and a report of that conference was issued on May 21, 1974.

Hearing was held in Washington, D.C. on August 8, 1974, at which Registrant was represented by Edward H. Hannes, one of its officers, and Respondent was represented by Anthony O. Garvin. Briefs were filed by the Registrant and Respondent on September 19, 1974, and replies on October 4, 1974.

Procedural Matter

1. Uniform date: Throughout this proceeding, Registrant has urged in various ways that this proceeding be delayed and a uniform date established for all registrants whose products will be subject to the testing protocol discussed herein, for renewal of registrations. To do otherwise, it is argued, would permit some formulators who may eventually fail to secure renewal to continue in business until various future dates, while this Registrant may have its registration cancelled now. A motion to this effect was denied by Order dated August 19, 1974, a request for reconsideration was denied by Order dated September 5, 1974, and finally a request for certification of the appeal to the Administrator was denied by Order dated September 25, 1974.

These orders are reaffirmed herein.

2. Post-hearing evidence: With its brief, dated September 14, 1974, Registrant tendered a copy of a new study by the Warf Institute, Inc., dated August 12, 1974 (designated as Ex. AA-1), subsequent to the close of the hearing. Respondent, by supplemental brief, dated September 25, 1974, objects to such date submission. Registrant, did not petition for leave to file the new study, explain the circumstances, or otherwise justify its exceptional request. Accordingly, Respondent's motion will be granted, and the "Exhibit AA-1" is stricken from the record.

Preliminary Statement

Registrations were first issued to Registrant for its product 707-X (EPA Reg. No. 1193-17) on April 23, 1954 and for 707-Warfarin

(EPA Reg. No. 1193-48) on May 11, 1961 at a time when no efficacy data were required for registrations of the five-year renewals. Subsequently, efficacy data requirements were established and on July 3, 1972, a five-year renewal notice was sent to the company requesting submission of efficacy data. On January 8, 1973, the test protocol was also sent to aid it in obtaining the correct efficacy data. Not having received the data from Registrant by December 1973, the Notice of Intent to Cancel EPA Regs. Nos. 1193-17 and 1193-48 was issued January 11, 1974. The company supplied data on January 11, 1974,[1/] which EPA considered and still considers as not meeting its requirements.

The basic issue herein is the testing protocol which Registrant vigorously contends is not an acceptable measure of efficacy of rodenticides for home usage. Registrant does not contend that its products have met, or could meet, the established testing protocol.

The Evidence

Respondent

Evidence was presented on behalf of Respondent by Herbert S. Harrison, Acting Chief of the Insecticide-Rodenticide Branch, Registration Division; John A. Ludeman, Head, Safety and Biological Section, Chemical & Biological Investigations Branch of the Technical Services Division; and

---

1/ It is contended this data was first submitted on June 15, 1973, but EPA had no record of its receipt at that time.

Paul M. Ochs, Criteria and Evaluation Division. The latter is an advisor to the Rodenticide Subcommittee of the Chemical Specialties Manufacturing Association, advisor to the Bird and Rodent Control Committees of the National Pest Control Association, and a member of the Interagency Rat Control Committee.

Registrant was represented by Edward H. Hannes, its Secretary, as both counsel and witness. He has had 39 years experience in the pesticide field and studies trade publications but has no formal scientific or legal training.

According to Mr. Harrison, EPA established a new policy in 1972 requiring all new applicants seeking registration for products containing anticoagulants for the purpose of controlling commensal rodents to submit data to prove that their product will be effective for the purposes claimed on the label. For products previously registered, the same requirement pertains only at the time the five-year renewal becomes effective unless such tests have previously been submitted.

Basically, the test protocol involved with such products requires that 10 female and 10 male rats and/or mice be used in a 15-day feeding study to determine the effectiveness of the product. The standard also requires that at least 90% mortality and 33% rodent acceptance be achieved during this 15-day study.

This type test is necessary since rats and mice may be bait shy for various reasons and, although it is known that anticoagulants will

kill rodents that consume it, it must be certain that they do, in fact, eat it. This requires that the product be acceptable to rats and/or mice.

The EPA test method for multidose rat and mouse baits is based on established information and good pest control practices. Mice are nibblers. They will nibble from one food source and go to subsequent food sources, nibbling from each as they go. This means that it is difficult to get the mouse to consume enough toxicant to cause mortality.

Rats are suspicious of any new article (including food) 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, he will associate that with his food and thereby cause the remaining population to shun that food source.

Sufficient acceptance of a multidose bait is necessary because the target animal must eat sufficient quantities of the bait over a minimum of 4 to 8 day period to kill the animal. The length of the period depends upon susceptibility of individual animals.

The 33% acceptance figure was established as follows. First, in some of the original development work done with warfarin at Purdue University, acceptance of the test bait in excess of 33% was normally achieved in laboratory experiments. Therefore, 33% was adopted as a reasonable minimum acceptance level for a bait that is properly formulated. At this acceptance level, the target species would be consuming twice as much EPA Control Bait as the toxic test bait.

Secondly, based on studies similar to those reported by Bentley and Larthe (1959. J. Hygiene 57:136-149), it was possible to calculate the amount of toxicant that a rat or mouse would need to consume every day for a period of 5 or 6 days to be killed (1 milligram toxicant per one kilogram rat weight). For a 250 gram rat, the minimum size required in the EPA test, the animal must consume .250 milligrams toxicant per day for 5 or 6 days to achieve 100% mortality. Based on feeding studies with one alternate food source, at least 17% of the toxic test ration would have to be consumed to kill 90-100% of the rats. However, the minimal acceptance for laboratory tests was adjusted to 33% to allow for the reduced consumption when more than one other food source is available, as is most often the case in actual use situations. This adjusted figure is substantiated by field studies conducted by Barnett, Bathard, and Spenser (1951, Ann. App. Bio 38:444-463). Under normal use conditions, they found that consumption of unpoisoned bait was reduced 50% when several alternate food sources were present.

Based on the type of information cited above, it is expected that a rodenticide achieving only 16% acceptance would be ineffective where competition from alternate food sources exists. To insure that the general public has a product that is efficacious under a wide range of actual use conditions which frequently includes the presence of alternate food sources, it is considered that the 33% acceptance requirement is valid.

EPA has tested registered products in its own laboratory that exceed 50% acceptance. Such is proof that a product properly formulated can exceed our efficacy requirement of 33% acceptance.

The efficacy data submitted by Registrant (Registrant Ex. No. 2) is limited to a summary statement of tests performed by WARF Institute on 707-X and 707-Warfarin but which are not in accordance with the EPA test protocol, and do not provide adequate information to establish the effectiveness of these products.

The tests conducted by WARF Institute Incorporated, were in effect preliminary tests for the purpose of determining whether an anticoagulant multidose rodenticide would perhaps be effective. If the preliminary tests indicate that the anticoagulant is significantly inadequate, the complete tests are not run. According to WARF, preliminary tests showed that the two 707 Company products had no possibility of complying with the minimum standards established by EPA. Therefore, complete tests were never completed.

WARF completed 3 preliminary tests that were designated as Test 1, Test 2, and Test 3. The latter two tests were represented as corresponding to the Warfarin product registered under EPA Reg. No. 1193-48, and Pival registered under Reg. No. 1193-17 respectively. Test 1 did not correspond to any registered product. The preliminary Warfarin test (test 2) indicated 8% acceptance and 70% mortality after 6 days. The Pival preliminary test (test 3) indicated 16% acceptance and 100% kill. Under the EPA test (15 day test) a minimum of 33% acceptance and 90% mortality is required. The data were also unacceptable because they lacked the following: tests on female rats (an important requirement due to the varying acceptability of baits among males and females), test on male

and female mice, the individual records of daily consumption and mortality, starting weights of the individuals, and a chemical analysis of the test ration. Furthermore, the test was a six day test rather than a fifteen day test with a five day observational period for survivors.

In addition, the 707 Company failed to submit the raw data substantiating the results of the tests performed by WARF, although EPA requires the submission of such data.

Mr. Ludeman further explained the test protocol which was designed to measure acceptability of registered rodenticides in comparison to a standard cereal control diet, and to measure the total mortality achieved after fifteen days of animal exposure to the rodenticide. The test is terminated if a 100% mortality occurs in less than fifteen days.

A standard bioassay test can be conducted with any number of test animals, but a ten-animal sample is considered adequate for statistical analysis. Because some toxicants react differently with one sex than they do with the other, the EPA protocol requires 10 animals of each sex per test. This number is sufficient statistically and is economically reasonable. The procedure now in use was developed over a period of years by biologists experienced in the development of rodenticidal baits and toxicants. It has been tried and adopted as satisfactory by independent and government laboratories engaged in rodenticide testing and developmental work.

One of the most important factors of a satisfactory anticoagulant rodenticide is the acceptability by the target species. This factor cannot be measured except by presentation to the target species. The formulation must be sufficiently attractive to entice an initial feeding by the rat or mouse, and also to make it return for a minimum of three additional daily feedings. By the fourth day the animal begins to feel ill and almost stops eating. If a sub-lethal dose has been ingested, the animal recovers but will refrain from eating the anticoagulant bait if other food is available. For this reason, it is important that only the most attractive baits be used when rat control is undertaken.

Research biologists have long known that rodenticide acceptance in the field is lower than recorded under laboratory conditions. In the laboratory the animal is closely confined with a restricted choice of food. His proximity to the rodenticide and the control diet is the same, so little effort is necessary for it to feed. In the field, in contrast to the laboratory, the animal has a variable choice of foods, usually in plentiful supply when compared to the amount of rodenticide applied to the area. In addition, it is conditioned to feeding on the pre-existing foods.

When the original anticoagulant research was conducted in the mid-1940's, investigators such as Dr. D. A. Spencer, Glen Crabtree, and Galen Oderkirk used 33-1/3% as their minimum acceptance for anticoagulant rodenticides. This acceptance factor was not difficult to attain and cereal formulations made from selected ingredients exceeded the 33-1/3%

figure. This meant that an anticoagulant bait need be only 1/2 as attractive as the competitive foods. Prior to this time, rodenticides containing acute toxicants had to equal or be more attractive than competitive foods if satisfactory control was to be achieved. Ludeman conducted some of the early field tests with Compound 42 (later named Warfarin) using formulas furnished by the USDI Fish & Wildlife laboratory at Denver, and found them to be very satisfactory. As he recalls, all were cereal baits containing at least two different ground grains. These were experimental formulations but must have passed cage tests prior to being subjected to field testing.

A bait that is accepted at the 16% level would produce a much lower acceptance under field exposures. Unfortunately the formulator cannot know what competition his baits will encounter when used, nor the skill of the user. Even the best bait can fail to produce satisfactory control if improperly applied. It can be assumed that most household users have little skill in the use of rodenticides. The label provides basic information but cannot thoroughly cover the problems in the space available. Because of the variability of use conditions, the best quality of bait has the best chance to produce the highest mortality. The production and sale of low quality baits is not only a disservice to the public, but can lead to the creation of bait-shy rats. This has already been reported from Europe and a few localities in the United States.

Judgment of efficacy of rodenticides from laboratory test results must be based upon how the bait compares with other baits. If chemical analysis shows the presence of the proper percentage of toxicant then

the deciding factor must be acceptance of the bait when exposed to the target animal. Ideally, this might be by actual use under natural conditions. Unfortunately, such testing would be inconclusive because of variability of test conditions, inability to obtain an accurate pre- and post-census of the population, and recovery of all dead animals would be impossible. The cost and time factor involved in repetitive tests would be prohibitive.

The acceptability of different baits varies considerably. The least acceptable baits tested during the past 12 years (approximately 2,500) show the lowest acceptance to be about 7%. The highest record is above 55%. The 33-1/3 figure used by the Animal Biology laboratory and by earlier biologists is slightly above the mid-point of the best and the poorest baits. Formulas achieving 33-1/3% acceptance have produced satisfactory control under field conditions when used under a variety of conditions and competitive foods.

When the Animal Biology laboratory was established in 1963, we were faced with the selection of a standardized laboratory diet. A diet was desired that could be made without special equipment and one composed of raw ingredients which could be purchased in any locality. They must also be foods commonly eaten by the target species. The formula finally selected was originally developed and used in the development of anticoagulant baits by the U.S. Fish & Wildlife Service. The bait contains 65% ground yellow corn; 25% rolled oats; 5% powdered sugar, and 5% corn oil. We purchase the corn meal and rolled oats from the USDA granary at Beltsville. The Department uses the materials for preparing experimental animal diets. The sugar and corn oil are

purchased from retail stores as needed. All ingredients are weighed on a Torsion Balance to the nearest gram, then are mixed in a Patterson-Kelly shell blender in 5-pound lots. The diet is mixed weekly and stored in a freezer until used. The finished diet is uniform in quality and no differences have been noticed in acceptance from week to week. The bait does not provide a balanced diet for rats, so is not suitable for feeding rats for a prolonged period. The addition of selected ingredients or varying its particle size could improve the diets' palatability, but we did not intend to use a highly competitive food for the standard control diet. No attempt has been made to compare the bait's palatability with other laboratory diets. It is readily apparent, on the basis of routine bioassays of registered rodenticides, that a better or poorer standard diet could be easily prepared. A standard diet should not necessarily be the best nor the worst, but should be consistent in ingredients, preparation, and stored under controlled conditions. This assures the use of a uniform product for bioassay purposes.

Occasionally, charges have been made that our test protocol is unfair. The charges are usually voiced by formulators whose products have failed to meet registration requirements, not by the manufacturers of registerable rodenticides. The test results show that commercial rodenticides can and do pass the test. The production of registerable rodenticides requires some knowledge of rodent habits and an awareness that both the active and inactive ingredients be of high quality. Rats are very selective, and will not eat inferior food if given a

choice. They can and do differentiate between a clean food and the same food containing 0.025% of anticoagulant. The latter is almost tasteless to humans, so the rats' sense of taste must be much better than ours. Ludeman feels that the test is fair and produces consistent results and he has received similar opinions from independent and government laboratories which have conducted studies using the EPA protocol.

While preparing his testimony, Ludeman reviewed EPA laboratory records regarding 707-X rodenticide. The product was initially tested in 1966. The rodenticide was accepted by rats at a rate of 27.5% of total food eaten. Mortality was 95%. Mice accepted the rodenticide at 21.3% of their total diet and mortality of 70% was recorded. During June 1967, EPA received, direct from the 707 Company, a sample of what was purported to be a representative sample of their current production. When tested with rats, consumption was only 7.0% with a mortality of 55%. As this was much lower than recorded for the earlier tests, Ludeman suspected that the sample might contain more than the registered 0.025% of pival. This has happened before when samples were supplied by manufacturers under similar circumstances. When the sample was analyzed, the chemist reported the sample did contain 0.35% pival instead of the registered 0.025%. Increasing the percentage of an anticoagulant always decreases acceptance and seldom increases mortality. Surprisingly, many manufacturers of rodenticides are not aware of this fact.

Based on his experience, Ludeman believes that low acceptance of the 707-X rodenticide can be attributed to a poor selection of the major inert ingredient. Corn meal is usually ground from corn which has had the

germ removed. The "flint" remaining when the germ is removed is not well liked by rodents. An examination of any rat infested corn storage will verify this observation. Acceptance of formulated baits can also be adversely affected by the use of tainted oil, sugar, impure toxicant, or from mixing the bait in unclean mixers. Even storage of the raw products where they can absorb foreign odors can lower acceptance of the finished bait.

Ludeman concludes that the acceptance of an anticoagulant bait is of utmost importance in determining its efficacy. Acceptance in use is, in nearly all cases, lower than indicated by laboratory tests, therefore, a rodenticide that is poorly accepted in the laboratory may well be ignored under field use. This will most likely occur when competitive foods are of great variety and high in acceptability. This can occur in the home as well as food warehouses, grocery stores, and other food handling establishments.

Mr. Ochs also explained the efficacy requirement and the basis of the testing protocol. A rodenticide-treated food and a standard cereal laboratory diet are offered in excess of the daily food requirements of the animal being tested (over 50 grams each cup for rats and over 20 grams each cup for mice). The gross weight of each cup and its contained food must be determined and completely replaced daily. The position of the bait and laboratory diet cups in the cage are reversed every twenty-four hours to counter any position preference by the test animal. The test animal must have a free choice between treated and untreated food.

Records must be kept on the daily food intake (consumption), mortality, starting weight, and sex of individual animals under test. The test product is made available for 15 consecutive days with an additional five days observation period for survivors. In order to demonstrate a product's effectiveness, the Agency requires at least 90% mortality and 33% bait acceptance be achieved during this 15 day study.

The active ingredients in the products in this proceeding are Warfarin and Pival. Both of these ingredients are anticoagulants. That is they interfere with the clotting mechanism of the blood and cause an animal to bleed to death from internal hemorrhaging.

Studies indicate that a single dose of an anticoagulant compound may not be effective in producing death even though the dose is extremely high. Hayes and Gaines (1950) concluded from their study of Warfarin that "all rats withstood a single dose of Warfarin at the rate of 50 mg/kg." Work carried out by the Ministry of Agriculture, Tolworth, Surrey indicates that single injections of 100 mg/kg Warfarin in rats produced only 13% mortality in the test animals.

These and other studies indicate that anticoagulants must be consumed in sufficient quantities over a period of days to produce a 90% mortality rate. Hayes and Gaines (1950) established 5 mk/kg (or 1 mg/kg/day) as a critical level by intubing Warfarin into white laboratory rats daily for 5 consecutive days. This procedure produced 90% mortality in 2 to 12 days. However, the same level given on alternate

days produced only 70% mortality in 5 to 13 days. J. P. Saunders (unpublished data) produced 83% (5/6) mortality in 7 days dosing rats with Warfarin at 1 mg/kg/day for five days. However, at 5 mg/kg/day for 5 days he produced 100% mortality in 7 days. Steiniger is quoted by Bentley and Larthe as reporting 0.68 mg/kg/day Warfarin for 5 consecutive days as a chronic LD_{50} for Rattus norvegicus. A Japanese study indicates 3 consecutive oral doses of Warfarin at 1.5 mg/kg/day produced only 40% mortality in 10 days (personal communication).

Since sufficient quantities of an anticoagulant compound must be consumed over several days, bait acceptance is critical in evaluating the effectiveness of products containing either Warfarin or Pival (Dykstra, U.S. Dept. of Interior). Acceptance of a bait depends on the type of active ingredient and the type of bait material used in the product. The fact that a product contains Warfarin or Pival does not assure that it will be effective, although the toxicity of these anticoagulants has been adequately established. This is because the acceptability of individual baits varies among products (Palmateer). Each product must, therefore, be tested to assure that it is accepted. If rats fail to consume sufficient quantities of a product under conditions of a laboratory it is doubtful that such product will be adequately consumed when placed in a rat's natural environment.

Bait materials in general must be more acceptable to the target animal than those food sources which are already established in their environment. This is especially true of anticoagulant baits since they must be consumed over several days in order to produce

their effect. Rats as well as other animals, also exhibit suspicion of anything new placed in their environment, anticoagulant baits in particular, because of their manner of use, must be more acceptable than existing food sources and overcome this suspicion, and keep the rat returning until a lethal dose is consumed.

Unlike insecticides which contaminate the insects total environment so that the insect has little or no choice as to whether or not the toxicant is consumed or touched, rats and mice nearly always have a choice of food sources. Any bait materials therefore, must be equally or more acceptable than their existing food sources. Again anticoagulants in particular must be highly acceptable since repeated consumption is required to produce mortality.

There are a number of other variables which may affect the acceptability of a rodenticide. There appear, for example, to be differences in the effectiveness of anticoagulants among different species of rats. In particular, roof rats (rattus rattus) are not as susceptible to Warfarin as are Norway rats (rattus Norwegicus). Doty states that Norway rats require an average total of 23 percent of its body weight of the poisoned food to produce death, compared to 39.1 percent for the black rat and 43.4 percent for the alexandrine rat, resulting in an average total of consumption of 36.3 percent for the rats tested. Work by Bentley and Larthe (1959) also show considerably higher consumption of Warfarin (0.025%) in unrestricted feeding tests was required to produce mortality in roof rats than in

Norway rats. All Norway rats were killed in this study within seven days at levels of consumption of Warfarin ranging from 7 - 16.3 mg/kg/day after 3 day exposure to treated bait while all roof rats were not killed until the seventeenth day at levels ranging from 5.3 - 14.2 mg/kg/day after 12 days exposure.

Similar species differences have been observed in studies of the effectiveness of Pival. Saunders (unpublished data) and the Public Health Service Report 1952 indicate Pival less toxic to Norway rats than Warfarin. Saunders indicates 10 mg/kg/day (5 oral daily doses) of Pival produced mortality in 5 of 6 animals in 7 days. The Public Health Service Report states 10.3 mg/kg Pival as the lowest concentration which killed all the Norway rats. The corresponding concentration for Warfarin is 3.3 mg/kg. Roof rats in the Public Health Service Report appear more susceptible to Pival than to Warfarin. The stated critical levels are 7.6 and 18.7 mg/kg Pival and Warfarin respectively, mice (mus musculus) also are reported more susceptible to Pival than to Warfarin. The critical levels are indicated as 4.2 mg/kg for Pival and 5.0 for Warfarin. Hayes and Gaines (undated report) indicate critical levels as 4.2, 18.1 and 5.5 mg/kg of Warfarin for Norway rats, roof rats, and house mice and 10.3, 17.0 and 4.3 mg/kg of Pival for those species respectively. Bonnet, Mau and Gross (1951), however, indicate house mice (mus musculus) fairly resistant to Warfarin requiring an average of 72.2% of the total consumption of Warfarin treated bait to produce mortality in an average of 8.6 days.

In addition, there appear to be differences in acceptability between sexes. Published data from WARF Institute (1974), indicate that there is a difference in the acceptability of rodenticides between males and females. One series of tests indicate that males consume more than females. Other tests indicate the opposite reaction. A third study with wild house mice also reflect different acceptance rates between sexes with females consuming slightly less. Because of these observed sexual differences, no accurate prediction of the acceptability of a product can be made from tests conducted solely on one sex. Consequently, the Agency requires registrants to submit efficacy data derived from tests conducted on both sexes. Without data on the acceptability of a product to both sexes, the Agency can not determine whether a product will be effective in actual use.

As noted previously, bait acceptance is critical in testing anticoagulant rodenticides since repeated consumption is required to produce mortality. The 33% acceptance requirement was established to assure that sufficient quantities of a rodenticide are consumed to produce mortality. The selection of 33% as the acceptability requirement was based primarily on data indicating that the quantity of anticoagulant consumed may decline appreciably in actual use. Findings of Barnett, Barthard and Spencer (1951) indicate bait consumption may drop 50% in the presence of good alternative food sources. At 33% acceptance anticoagulant baits can probably withstand a reduction of 50% consumption when placed in normal conditions of use.

Norway rats normally consume from 7.5 to 15% of their body weight per day (Chitty and Shorten, 1946; Jackson, 1965; Srivastave, 1964; Brooks, 1973). The general rule of thumb used is 10% of their body weight. In tests conducted at our Animal Biology Laboratory when no toxicant was used the total consumption for Norway rats averaged between 9.0% and 9.7% of their total body weight per day. Under the same conditions of test but when a toxicant is used consumption dropped to 6.4 to 7.4% of their total body weight per day. This drop in consumption is caused by sick and dying animals.

A bait containing 0.025% toxicant consumed under laboratory conditions at 33% of the total food intake would produce approximately 6.0 mg/kg/day. Assuming an average of 7.4% consumption to body weight, using a 200 gram rat, the rat would consume 1.2 mg of toxicant per day. A bait consumed at 16% of the total food intake under laboratory conditions would produce approximately 3.0 mg/kg/day. (Assuming an average of 7.4% consumption to body weight a 200 gram rat would consume 0.6 mg/day.) If both baits were placed into a rat's normal environment and consumption of each were reduced by 50% because of alternative food sources (33% reduced to 17.5% and the 16% reduced to 8%) the data from Hayes and Gaines indicate the bait consumed at 17.5% should still be effective while the bait consumed at 8% may not. (The data from Japan, however, indicate that neither would be.) Actual laboratory studies showing only 8.0 $\pm$ 0.5% acceptance produced 60 to 100% mortality on Albino rats in 15 day studies. For roof rats such baits would not be expected to be effective (Hayes and Gaines, undated report, Doty, and Bentley and Larthe).

Although a product consumed at less than 33% acceptability may produce 90% mortality in laboratory experiments, the above data indicates

that such a product may not be effective in actual use against Norway rats and probably would not be effective against roof rats. The Agency therefore determined that 33% acceptability in laboratory studies is necessary to insure that an anticoagulant pesticide will be effective in actual use.

A 33% acceptability level is not an impossible or unrealistic requirement. Many rodenticides have met and even exceeded this criteria. In a personal communication from the former supervisor of the Animal Biology Laboratory the following information was provided: For Warfarin out of 54 official samples tested 28% met or exceeded the criteria; for Pival out of 39 tests 44% met or exceeded the criteria. In data to be published by Steve Palmateer (1974) out of 72 tests with Pival 26% meet or exceed the criteria, for Warfarin out of 157 tests 9% meet or exceed the criteria.

The use of a control bait to test the acceptability of a product is necessary to determine whether a product will be accepted when rodents are given a choice of food sources. Standard inert ingredients (65% corn meal, 25% rolled oats, 5% powdered sugar, 5% vegetable oil) used by the Animal Biology Laboratory for testing multiple dose rodenticides are suggested as the control diet.

There are a number of reasons for using grain rather than some other bait material for anticoagulant baits. Anticoagulant baits must be available for several days and sometimes weeks. Grain is the most stable bait available. Anticoagulants also may affect pets and other warm

blooded animals when consumed in sufficient quantities. If meat or fish are used as a bait base for anticoagulants the hazard to pets would be greatly increased. Meat and fish also will remain acceptable to rats for only a few hours where grain remains acceptable for days.

The formulation used by the laboratory as a challenge diet is a realistic challenge. The ingredients generally are available to rats in most situations. The form may not be the same but the general ingredients are readily available, to humans and to rats. The fact that these ingredients are readily available is another reason that this challenge was selected. These materials can be purchased at any grocery store in the U.S. and our challenge bait can generally be duplicated.

Ochs concludes that in order to protect the public, the Agency should require registrants to submit information demonstrating the efficacy and safety of their products. Efficacy of anticoagulant rodenticides is dependent upon small doses over a period of several days. Acceptance is therefore critical. However, acceptability may be affected by several variables. Rats and mice, for example, vary in their susceptibility to Warfarin and Pival. Acceptance also varies between sexes. Consumption, moreover, declines significantly when alternative food sources are available.

For these reasons, the Agency has established a 33% acceptability requirement in addition to its 90% mortality requirement. Baits meeting 33% acceptance under laboratory conditions can withstand a 50% reduction in consumption when placed into a rat's environment and still be expected to be effective. Rodenticides achieving less than 33% acceptance may not be effective against Norway rats and probably will not be effective

against roof rats. An acceptance rate of 33% is obtainable and has repeatedly been achieved by other bait manufacturers.

Registrant

Registant attacks the testing protocol on the two basic grounds,[2/] (1) the test has been wrongly and unscientifically established and (2) the EPA standard bait is lacking in uniformity from laboratory to laboratory and render the tests meaningless. Finally, as previously noted, that all registrants[3/] should have a single "cut-off" date for five-year renewals and submission of efficacy data. Its presentation was by Mr. Hannes, who as previously noted, does not possess formal scientific training, and consisted almost wholly of questioning or disagreeing with the EPA position. The only affirmative evidence offered consisted of the WARF Institute report of tests made on samples submitted in April and May 1973. (Registrant's Ex. No. 2.)

Mr. Hannes challenges the 33% acceptance requirements as ill founded. He pointed out that EPA witness Harrison made an incorrect statement in explaining the basis of the 33% standard. Mr. Harrison stated: "This adjusted figure is substantiated by field studies conducted by Barnett, Barthard, and Spenser (1951, Ann. App. Bio. 38:444-463)." Mr. Hannes

---

2/ The grounds are stated as hypothetical questions, but are treated herein as positive contentions.

3/ While not clearly defined, it is assumed to refer to all registrants subject to the particular testing protocol discussed herein, the number of which are not disclosed of record.

submitted a page from that article (att. to Registrants Ex. No. 1) in which the authors discuss the rat population in conjunction with a field study the authors made. But the authors apparently made no field studies of their own on the subject of rat population, citing rather "Emlem et al. (1949)" who believe the stated fact and "Chitty, unpublished, for a full discussion." It would obviously have been more correct if Mr. Harrison had stated: "This adjusted figure is substantiated by authorities cited in field studies conducted by Barnett, Barthard, and Spenser."

Mr. Hannes also points to the WARF Institute Study (Registrant's Ex. No. 2) which indicated that with respect to 707-X, which contains pival, a 100% kill was achieved in 6 days with only 16% acceptance.

When rats enter a home and locate and consume foods, the homeowner who observes this will cover the food or store it where rats have no access, and then the bait becomes the only available food.

The 707-X product bears on the label an offer of "money back for empty can if it does not kill and control rats" but the company has never been asked for a money back. Moreover, in the urban areas where its product is used, the feed-back from customers is that the product always gets rid of their rodents. Hannes believes that in the home the rats consume nearly 100% of the diet in rodenticide although when they first enter, they will consume other foods. Hannes' wife would cover bread, bananas, and the like if they were once attacked. Therefore, Hannes believes the 33% might be necessary where there is restricted diet, such as in the fields or outdoors, but not in the home.

The product 707-Warfarin label does not carry the money-back offer and the sales of that product are to small Mr. Hannes is willing to drop it.

Mr. Hannes also contends there is no uniformity of the EPA standard bait, which consists of 65% of corn meal, 25% rolled oats, 5% sugar, and 5% corn oil. Further, he considers this unsuitable for determining efficacy of rodenticides used in the home where other types of food are commonly present.

Findings of Fact

1. Acceptability of the bait is of critical importance to the effectiveness of anticoagulant rodenticides.

2. The acceptability of anticoagulant rodenticides is affected by several factors, including the sex of the animal, the species of the animal, the availability of alternative food sources, and the ingredients of each product.

3. In actual use, the consumption of an anticoagulant rodenticide may decline by as much as 50% from that achieved in laboratory tests.

4. It is reasonable for EPA to require tests of the acceptability of anticoagulant rodenticides because of the critical nature of acceptability to the effectiveness of such products.

5. A standard of 33% acceptability is reasonable in view of the fact that acceptability may decline by as much as 50% in actual use.

6. The standard laboratory diet used in efficacy tests provides a reasonable test of acceptability.

7. The Registrant failed to demonstrate the existence of statistically significant variation in the acceptability of the standard diet prepared by EPA.

8. The only objective efficacy data submitted by the Registrant were the results of tests performed by WARF Institute in 1973 but these were not conducted according to the test protocol established by EPA.

9. The tests conducted by WARF Institute indicate that neither of the Registrant's products are able to meet the efficacy criteria established by the Respondent.

10. The Registrant has not submitted data on female rats or any other evidence regarding the effectiveness of its products against female rats.

11. The Registrant has failed to establish that its products are effective against male and female rats or male and female mice in actual use.

12. Since the Registrant failed to submit sufficient objective data to establish the effectiveness of its products, the registrations of "707-X," EPA Registration No. 1193-17, and "707-Warfarin," EPA Registration No. 1193-48 should be cancelled.

13. The Registrant agreed to the cancellation of the registration of the product "707-Warfarin," EPA Registration No. 1193-48.

Discussion

The challenge of the 33% basis for acceptance required by the test protocol is not supported by the fact that witness Harrison referred to a published article in which a source was stated to be a

"belief." Numerous other supporting statements were cited by the witness and by witnesses Ludeman and Ochs. These all point to a rational basis for the standard set. The 33% acceptance basis was fully supported by each of the three EPA witnesses, and each of which was fully qualified through education and experience as experts in this field.

The WARF Institute report on which Mr. Hannes relies so heavily is not acceptable under the test protocol, primarily because it failed to include female rats. That the sex of the test animals is an important factor, leading to the requirement that both males and females be included, is well established in this record. Of equal importance is the fact that Registrant did not comply with the Report of Prehearing Conference that it make supplemental and explanatory information available from the Institute concerning the report. Respondent also faults the study because it was for only six days, but with respect to Pival, 100% mortality had been achieved at that point and the test was understandably terminated.

While Mr. Hannes asserts his belief that test samples may vary when mixed in various parts of the country even when the EPA formula for standard bait is followed, there is no evidence of record to support such a contention. Were this true, of course, test results would vary even of an identical product due to variance in the standard of comparison.

Ultimate Conclusion

The products here in question have failed to meet the test protocol and Registrant has accordingly failed to demonstrate their efficacy. Pursuant to Section 6 of the 1972 FIFRA (7 U.S.C. 136d) EPA regulations,

Section 162.10(i) [4/] the registrations should be cancelled.

IT IS ORDERED, That the Registration of 707-X, EPA Reg. No. 1193-17 and 707-Warfarin, EPA Reg. No. 1193-48, are hereby cancelled.

Frederick W. Denniston
Administrative Law Judge

October 29, 1974

4/ Issued under the former FIFRA (7 U.S.C. 135 et seq.), but continued in effect by Section 401 of the 1972 FIFRA.

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).