UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE REGIONAL ADMINISTRATOR

In the Matter of	)	
	)	
VRP Corporation,	)	I.F.& R. Docket No. IX-267C
	)	
Respondent	)	

INITIAL DECISION

Preliminary Statement

This is a proceeding under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), Section 14(a), (7 U.S.C. 136 l(a)), instituted by a complaint issued January 9, 1980, by the Director, Enforcement Division, Region IX, United States Environmental Protection Agency, against VRP Corporation, the Respondent herein, for alleged violations of the Act and the regulations issued thereunder. Specifically, the complaint alleges that Respondent sold numerous electromagnetic pesticidal devices which were ineffective in controlling pests and that the devices were misbranded in violation of Section 12(a)(1)(F) of the Act (7 U.S.C. 136j(a)(1)(F)) "since its labeling claims of efficacy are false and misleading." The complaint proposed a civil penalty in the total amount of $10,000, the statutory maximum for two violations, although many more violations allegedly occurred.

Respondent filed an answer in which it denied that the product involved, the Ergon Pest Control System, was misbranded, that it violated the Act as charged, and that it was subject to the proposed penalty. The parties

submitted prehearing materials pursuant to section 168.36(e) of the rules of practice.[1/] A prehearing conference and hearing were held April 13 and 14-16, 1981, respectively, in Los Angeles, California, before Herbert L. Perlman, Chief Administrative Law Judge, United States Environmental Protection Agency. Complainant was represented by Michael P. Kerner, Attorney at Law, Enforcement Division, Region IX, United States Environmental Protection Agency, and Respondent was represented by Louis A. Weisenberg, Attorney at Law, Fountain Valley, California. At the hearing, Complainant presented six witnesses and introduced numerous exhibits into evidence. Four witnesses testified on behalf of Respondent and it also introduced numerous exhibits into evidence. After the hearing, the parties submitted proposed findings of fact, conclusions of law, and a proposed order with supporting briefs.

Chief Administrative Law Judge Perlman died on October 28, 1981, before having rendered an initial decision in this matter. Consequently, the Acting Chief Administrative Law Judge, by order dated November 13, 1981, designated me, an Administrative Law Judge with the United States Environmental Protection Agency, to succeed Chief Administrative Law Judge Perlman as the presiding officer. I have reviewed the entire record and the briefs submitted by the parties, and hereby render this initial decision.[2/]

1/ The Parties stipulated that the rules of practice found at 40 CFR 168.1 (1979) (39 Fed. Reg. 27659 (July 31, 1974)) are applicable to this proceeding. See Transcript of testimony ("Tr") at 6.

2/ See 5 U.S.C. 554(d): "The employee who presides at the reception of evidence pursuant to Section 556 of this title shall make the. . .initial decision required by Section 557 of this title, unless he becomes unavailable to the agency."

All proposed findings of fact inconsistent with this decision are rejected. The citations to the record are not intended to include all portions of the record relating to the point discussed but only some of the salient evidence on the point.

Findings of Fact

1. Respondent, VRP Corporation, is a corporation doing business in Los Alamitos, California and manufactures and distributes in commerce an electronic device intended to eliminate and control infestations of rats and mice known as the Ergon Pest Control System (hereafter referred to as the "Ergon device"). Answer; EPA Ex. 6; Tr. 421.

2. During 1978-79, VRP sold and shipped approximately 4,500 Ergon devices. Sales were made through its sole distributor, Rodent Ridder, Inc., of Chillicothe, Missouri, to whom the devices were shipped on consignment. Resp. Ex. 6, Tr. 16-18.

3. Included in the packaging of each device shipped by VRP were installation instructions and sales literature. Tr. 19-20, 394, 418-422.

4. The sales literature that accompanied the Ergon device in sales made during 1978-79, included the following pesticidal claims:

> This Pest Control unit is manufactured by a concern which specializes in research upon and the manufacture of electromagnetic pest control systems and devices. The unit is designed to eliminate and control infestations of rats and mice wherever they occur in farm buildings, residences and field acreage. Initial use, generally during the first 90 days after installation, eliminates an existing infestation, and continued use thereafter effectively controls the area and prevents reinfestation.
>
> Soon after this unit is installed and plugged in, an electronically generated, Magnetic Frequency Field spreads out under the ground in a circular pattern around the point of installation. Depending upon the type of terrain, the type of soil and the amount of moisture present in the ground the Magnetic Frequency Field will cover up to 5 acres (a radius of 2 1/2 acres from the point of installation) in some cases, it will cover more than 5 acres.
>
> . . . .

> Between the 60th and 90th day after installation, both a decrease in rat and mouse activity and a decrease in the actual number of rats and mice in the area covered by the Magnetic Frequency Field should be noted.
>
> . . . .
>
> The Pest Control unit is guaranteed to eliminate and control infestations of rats and mice. . . .(EPA Ex. 6) 3/

5. The Ergon device is comprised of a metal case housing three coils mounted on a 3/4" diameter rod. The rod extends approximately 5" or more outside the base, and is called the "repeller bar." The device is equipped with thermal switches which randomly open and close the power supply to the coils, and a flasher which interrupts the flow of the current to the coils at a rate of about 60-65 times per minute. Thus, whatever electromagnetic radiation emanates from the device is produced intermittently. EPA Ex. 8; Tr. 428.

6. Electric power to the Ergon device is supplied from a 115 volt, 60 hertz ("Hz") frequency power supply. The device, when the switches are closed and power is supplied to the coils, generates predominantly a 60 Hz frequency electromagnetic field. When the thermal switches open, shutting off the current, the collapsing electromagnetic field also produces very short pulses over a wide spectrum of frequencies known as "white noise pulses." EPA Ex. 8; Tr. 57, 577.

7. Measurements made of the strength of the electromagnetic field ("EMF") produced by the Ergon device disclosed a maximum of 14 volts peak-to-peak of 60 Hz frequency at the repeller bar with the EMF decreasing rapidly with the distance from the unit. At a distance of 3 meters (approximately 10 feet) from the device the EMF of the 60 Hz frequency electromagnetic

3/ "EPA" exhibits are referred to in the transcript as "Complainant's Exhibits." The claims in EPA Ex. 6, a sales letter under Respondent's name, are identical to the claims made in the sales letter sent out by Respondent under Rodent Ridder's name. See EPA Ex. 22.

field will be much less than the earth's magnetic field, which is approximately 0.5 gauss. EPA Ex. 8; Tr. 83-84, 124, 575-576. The electromagnetic field also significantly diminishes in strength as the frequency exceeds 60 Hz. Tr. 121.

8. The Ergon device does not generate an electromagnetic field of sufficient strength to repel rodents and is ineffective in eliminating or controlling rodent infestations.

Discussion, Conclusions and Assessed Penalty

The issue in this case is whether the Ergon device is effective in eliminating or controlling rodents. The EPA relies on its electronic analysis of the device and on biological testing done with devices which the EPA contends are substantially similar in their mode of operation and electromagnetic output for proof that the device is ineffective. Respondent contends that those tests are irrelevant because they were not performed with the Ergon device and because they were not properly conducted. Respondent also contends that biological tests with the Ergon device do establish that it can be effective in controlling rodents, and that this is corroborated by the actual experience of persons who have used the device.

One initial problem in evaluating the efficacy claims for the device is identifying the cause of the asserted pesticidal activity of the device. Respondent, in its sales literature, has claimed that the rodents are repelled by the "Magnetic Frequency Field" generated by the device.[4/] In its application to patent the device, however, Respondent described the device as "designed to create -- within the surface and subsurface areas

4/ EPA Ex. 6.

surrounding said device -- radiating sonic waves and physical vibrations which are transmitted outwardly from the positioned device over large areas."[5/] It appears, however, that Respondent believes that the repelling effect is caused in some way by electromagnetic radiations produced by the device and not to the production of any sonic waves or physical vibrations.[6/]

The EPA first had the device analyzed by experts at the National Bureau of Standards in order to determine its mode of operation and the nature of the electromagnetic radiation produced by it.[7/]

5/ Resp. Ex. 19.

6/ Mr. Riach, Respondent's president, testified that Respondent has never claimed in its sales literature that the Ergon device operates on rodents as an accoustical or a sound producing device, stating that he would not make such claims because "sound dissipates." (Tr. 351-352.) He further testified as follows (Tr. 362):

> Q. From those tests /conducted by McPete Systems/, what belief or understanding have you come to as to what may or may not be put out by your device?
>
> A. We have concluded -- not absolutely but to the best of our knowledge, feel that it is a current pulse.

Accordingly, it is not necessary to consider the evidence relating to the sonic output of the Ergon device or its physical vibrations. See testimony of Mr. Ira Leonard at Tr. 128-169.

7/ The National Bureau of Standards had previously analyzed several electronic pest control devices for the EPA in order to determine what their working principles are, whether they have any common characteristics which would allow grouping or classifying of similar units for biological testing, and whether it would be feasible to develop a standard test method for measuring and classifying the units based on the nature of the electromagnetic signals. EPA Ex. 9; Tr. 52.

Analysis showed that the device basically functioned by supplying a 115 volt, 60 Hz frequency current intermittently to three coils mounted on a magnetic steel rod which extended outside the box. The intermittent flow was produced by the operation of thermal switches and a flasher. Measurement of the strength of the electromagnetic field produced from the flow of 60 Hz current through the device disclosed that the strength decreased very rapidly with the distance from the unit and that at a distance of 3 meters or greater, the strength was much less than the earth's magnetic field.[8/]

Respondent produced no evidence which contradicted the above findings. Instead, Respondent endeavored to show that the findings were incomplete and did not accurately describe the electrical operation of the device. According to Respondent, the Bureau of Standards failed to test the electrical output of the higher frequency pulses which were generated by the device. Respondent's expert witness, Mr. Peters, explained the origin and nature of the higher frequency pulses as follows:

> Well, the broad band frequency does not emanate from the coils. . . .The broad band is generated by the action of the switches upon opening. There is some broad band interference generated as the switch closes, but it is of greater magnitude as the switch opens due to the back EMF, the collapsing of the field, the magnetic field, if you will, as the circuit is opened. . . . This generates a very, very short series of pulses before the voltage drops to zero.[9/]

Mr. Peters accordingly ran tests to measure the higher frequency current pulses emitted from the repeller bar. One test consisted of measuring the current as it flowed through a wire, one end of whch was

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8/ See Findings 6 and 7, Supra.

9/ Tr. 577.

attached to the repeller bar and the other end was soldered two feet away to a copper table that served as a ground.[10/] Mr. Peters described the test as "simulating" the operation of the device in the field, but he admitted that the conditions under which the test was conducted bore little resemblance to actual field conditions, since the wire offered far less resistance to the flow of electricity than the earth would have.[11/] The test did disclose instantaneous pulses in a wide band ranging up to 276 MHz. At the 60 Hz frequency, an instantaneous pulse of 80 amperes was measured, but the magnitude of the pulse decreased as the frequency increased. For example, at the higher frequency of 50 KHz the current measured had dropped to a magnitude of only 3 amps.[12/] As already noted, however, the magnitude of the current flowing through the wire could not really be considered as representative of the magnitude of the current that would be flowing through the earth which would offer far greater resistance to the current and so result in current pulses of far lower magnitude.[13/]

A second test conducted by Mr. Peters consisted of determining whether the Ergon device propagated any discernible signals at a reasonable distance from the unit.[14/] Again, the test was described as one conducted

10/ Resp. Ex. 7; Tr. 578.

11/ Tr. 605-606.

12/ Resp. Ex. 7 (data sheet, page 3); Tr. 601, 603. The pulse of 80 amperes in the 60 Hz frequency and the readings for the other cycles represented the magnitude of the current flowing through the wire. The magnetic field radiated from the repeller bar was of a considerably lesser magnitude. For example, the magnetic field radiated at the 60 Hz frequency measured only 1/1000 of a gauss and considerably less than the magnetic field of the earth. Tr. 598.

13/ Resp. Ex. 7; Tr. 606

14/ Resp. Ex. 25; Tr. 583.

under a typical field application, but again, the measurements were made not of the magnitude of the current disseminated through the earth, but of the current flowing through a wire.[15/] The highest current found in the field test was .0025 amperes, which was concededly a very small amount of current.[16/]

In conclusion, Respondent's testing of the electrical output produced by the higher frequencies simply confirmed the observation of Mr. Gordon that the strength of the electromagnetic field greatly decreases as the frequency exceeds 60 Hz, and that at that frequency the magnetic radiations were much less in strength at a distance of about 10 feet from the device than the earth's nominal magnetic field. While pulses of larger magnitude could be detected in the form of current flowing through a wire, such measurements have not been shown to be really representative of what current would actually flow through the earth. The efficacy of the Ergon device is not represented as depending upon rodents actually coming into contact with a wire attached to the device, but upon the magnetic field which is stated to radiate from the device.[17/]

The EPA did not rest its case solely upon evidence demonstrating that the Ergon device produces a very weak electromagnetic field. It also relied upon biological testimony done with similar devices to show that the Ergon device was ineffective. One biological test was done at the EPA's Animal Biological Laboratory at Beltsville, Maryland ("Beltsville test") with an

15/ Tr. 610-612.

16/ Tr. 604-605.

17/ EPA Ex. 6.

Amigo Phase 2, Model C 100 (EPA sample No. 148834) ("Amigo device").[18/] This device was constructed similar to the Ergon device in that it was contained in a metal case, which housed three coils mounted on a 3/4" diameter rod, the rod extending approximately 7 1/2" from the bottom.[19/] Mr. Gordon, the EPA's expert witness from the Bureau of Standards, who had investigated the operating principles of electronic pest controllers for the EPA, described the Amigo device and the Ergon device as having the same basic internal components and being very similar in the electromagnetic fields they generated.[20/]

In conducting the test, a test site and control site were established. At the test site, the test rats were placed in a wooden frame building erected on a concrete slab. The Amigo device was installed about one foot outside the building on top of a 10 foot pipe driven 9 1/2 feet into the ground. The device was connected by a three-prong plug to an electrical outlet on the exterior of the building, which had been grounded to the water pipes in the building. The test rats inside the building were within 10 feet of the device. The control site where the control rats were placed was a building located two miles from the test site and out of the range recommended for the device.[21/] Tests were run to determine whether the device stopped the rats from eating, drinking or breeding. The test results, when analyzed, showed that the device did not significantly

18/ EPA Ex. 15.

19/ EPA Ex. 23. Measurement of the D.C. resistance on the Amigo device and the Ergon device indicated that the number of turns of wire on the coils of both devices was very, very close. Tr. 125.

20/ EPA Ex. 8, 23; Tr. 74-75, 89, 125.

21/ Tr. 177-178, 191-192; EPA Ex. 15A.

affect the eating, drinking or breeding of the test rats.[22/]

Respondent contends that notwithstanding that the Amigo device is similar to the Ergon device in being designed to repel rodents by the intermittent generation of an electromagnetic field, the two devices are not comparable in their operation because of differences in their components and in the construction.

One difference which Respondent contends distinguished the Ergon device from the Amigo device tested was that the Ergon device has a flasher and resister while the Amigo device does not. As explained by Mr. Gordon, the flasher is used with the thermal switches to create the intermittent pulse signal. When the thermal switches are closed to allow the flow of current through the coils, the flasher interrupts the power supply at a rate of about 60 to 65 times a minute so as to produce a regular pattern of pulses during that period. The resister, which also acts as a heat-sink, contributes to the randomness of the pulses by affecting the opening and closing of the thermal switches.[23/] Neither of these components would appear to increase the strength of the electromagnetic field generated.

Still other differences which Respondent contends makes any comparison between its device and the Amigo device invalid are that the Ergon device employs thermal switches outside the coils while the Amigo device employs thermal switches adjacent to its coils, and the coils on the Ergon device

22/ EPA Exs. 15, 15A; Tr. 179-181. The eating trial showed no statistically significant difference at the 5 percent significance level between the control and test groups in the amount of food consumed, while the breeding trial showed no significant difference at the 5 percent level in the average weight of the pups at 7 days or the survival rate of the pups during the 7-day period from birth. The 5 percent level denotes only a 5 percent probability that the differences between the two groups could be attributed to the treatment with the Amigo device rather than to random variations not associated with the device. Tr. 180, 272-275. The water consumption of the test rats was higher than for the control rats, particularly during the pretest period but remained fairly constant during the test and appears to have been within normal limits. EPA Ex. 15A.

23/ EPA Ex. 8; Tr. 89, 117-118.

are wired in series while the coils on the Amigo device are assertedly "opposing."[24/] Respondent admits that the location of the thermal switch outside the coils decreased the risk of the Ergon device burning out, and that would also appear to be the principal reason for having the coils wired in series instead of opposing each other.[25/] In testing the Amigo device, however, there appears to have been no problem with having the device burn out or stop operating.[26/]

What the differences between the Ergon and Amigo devices seem to add up to is that the Ergon device is constructed to last longer in the field, and, possibly, because of the flasher, to emit its electromagnetic pulses in a somewhat more regular pattern. The differences, however, do not appear to alter in any material way the similarity in their electrical output which is intended to operate on the rodents and which, in each case, consists predominantly of an intermittent 60 Hz cycle electromagnetic pulse interspersed with very short higher frequency electrical bursts associated with the opening and closing of the circuit.[27/] Consequently, it is found that the two devices are comparable in their operation and that efficacy tests conducted with the Amigo device were probative of the efficacy of the Ergon device .

24/ It is not at all clear, however, that the coils on the Amigo device, when activated, would oppose each other. See Tr. 98-99.

25/ See Respondent's opening brief at 7; Tr. 346, 588. Respondent's expert witness, Mr. Peters, stated that having the coils opposing would nullify the electrical output, but this would happen only when the thermal switches by chance were activated simultaneously. Tr. 587.

26/ Tr. 181-182, 203.

27/ See *supra*, Findings of Fact 5 and 6.

Respondent further argues that there were flaws in the test procedures which nullified the results. Thus, Respondent asserts that measuring the daily aggregate water consumption of the rats instead of measuring each rat's consumption prevented drawing any statistically reliable conclusions about the effect of the device on the rats' water consumption. Nevertheless, it is reasonable to assume that if the device had affected the water consumption of a significant number of the test rats, this would have shown up in the aggregate data, and the water consumption would not have been as constant as it was over the 14-week period.[28/] Respondent also argues that the control rats in the drinking test were unreliable for comparison purposes because they drank much less water than the test rats during the pretest period.[29/] The lack of any significant effect of the device on drinking, however, could be ascertained in other ways besides the comparison with the controls, namely, by the fact that the water intake of the treated rats was not abnormally low at the beginning of the test and remained fairly constant during the test period.[30/]

28/ See EPA Ex. 15A.

29/ Mr. Palmateer, the EPA biologist who conducted the test, was unable to give an explanation for the lower water consumption by the control rats in the pretest period. Tr. 204-205. During the test period, the control rats increased their water intake to where their water consumption was similar to the treated rats. Tr. 205, EPA Ex. 15A.

30/ EPA Ex. 15A. Respondent also contended that covering the bottom of the tank in which the drinking test was conducted with wood shavings could insulate the rats from the effects of the device. Mr. Palmateer explained, however, that the rats, in order to drink, had to hop on a one inch metal pan resting on the bottom of the tank, so the wood shavings could not have affected the test. Tr. 207.

Finally, Respondent contends that the breeding studies were unreliable because many of the animals were pregnant when they were put into the study and two pairs of test rats never produced a litter during the pre-test period, the test period, or the post test period. Some of the rats were undoubtedly pregnant at the beginning of treatment in both the treatment and control groups.[31/] The important fact would seem to be, however, that the rats in both groups continued to breed during the test period and there was no siginificant difference between the control and treatment groups in the survival rate of the litters or the weight of the pups.[32/] As to the inclusion of two possibly nonbreeding pairs of rats in the treatment group, Dr. Pritchett did state that this biased the breeding data, but he did not eleaborate on how the bias would or could affect the validity of the data.[33/] Mr. Palmateer apparently did not regard the fact that two pairs of rats never bred as impairing the validity of the statistical computations or the conclusion that the treatment rats bred with vigor during the test period.[34/]

31/ Rats have a gestation period of about 21 days and litters were born in both groups during the first three weeks of the test period. Tr. 194-195; EPA Ex. 15.

32/ EPA Ex. 15.

33/ See Tr. 485.

34/ EPA Ex. 15. Respondent seems to find significant Mr. Palmateer's finding that the treatment rats bred with vigor during the test period. Mr. Palmateer explained that he was not attempting to draw any distinction between the control rats and the treatment rats in the vigor with which they bred. Tr. 200. In any event, for the Ergon device to encourage breeding which is what Respondent's argument suggests, would seem to be contrary to Respondent's claims for the device.

It is concluded, then, that the Beltsville study did produce data of sufficient accuracy to permit valid judgments to be drawn with respect to the efficacy of the Ergon device under the conditions which the test was conducted. Respondent contends further, however, that the test was not accurately representative of how the Ergon device would perform, since the rodents were insulated from direct exposure to the Ergon device by being housed in cages inside a wooden building, and there was no connecting wire between the test building and the device.[35/] Presumably, this argument is directed to the fact that Respondent's installation instructions recommend that where building are involved, the device, if it is installed outside the building, should be attached to or connected by wire to a gas or water pipe which feeds the structure, or attached to an electrical conduit on the outside wall or directly to a building with sheet metal walls.[36/]

35/ Respondent's brief at 9.

36/ EPA Ex. 6. The EPA contends that the device was connected to a feeder pipe since the electrical plug for the Amigo device which was tested was grounded to the water pipe which fed into the building. Tr. 192. The instructions, however, seem to recommend that the device be wired to a feeder pipe or to the building in addition to grounding the electrical plug. See EPA Ex. 6. The wiring would not seem to have any significant effect on the strength of the magnetic field generated. See Supra at 8-9. Respondent also argues that the test was not fair because wood is not conductive electrically, but relevancy of this is not clear since the wood would not appear to act as a barrier to the transmission of electromagnetic rays. Tr. 49.

Respondent accordingly presented its own tests to show that the device does have the capacity to repel rodents who are exposed to its electromagnetic radiations.

One series of tests were conducted by Dr. John F. Pritchett, an Associate Professor at Auburn University. The purpose of the test was to determine whether the device constitutes a "biological stressor", i.e., acts as a noxious stimulant which calls forth adaptative behavioral responses from the rodents like avoidance or withdrawal.[37/] Dr. Pritchett explained that stress will act to change an animal's endocrine system. When an animal is subject to stress, its pituitary gland liberates a substance known as ACTH or adrenocorticotrophic hormone which stimulates the adrenalin gland to produce corticoid, or corticosterone, hormones. Tr.439. An animal subject to acute stress (i.e., of short duration) will be very responsive to ACTH and increase its secretion of corticoid hormones which will assist it in adapting to the stress. Tr. 438. On the other hand, where the stress is chronic or of long duration, the adrenalin gland will not be as responsive to ACTH with respect to producing corticoid hormones.[38/]

The testing performed by Dr. Pritchett was broken down into Phase I, Part A and Part B, and Phase II.[39/] In the Phase I studies, rats were housed in individual galvanized cages which were placed on metal trays supported by four posts (referred to as a "multiple cage battery") with

37/ Resp. Ex. 26 at 5.

38/ Tr. 438-441.

39/ Phase I, Part A is reported in Resp.'s Ex. 2A; Phase I, Part B is reported in Resp.'s Ex. 8B; and Phase II is reported in Resp.'s Ex. 26.

the test animals being in a separate room from the control animals. An Ergon device was attached to a galvanized corner post of the cage battery which held the test rats and the repeller bar was clamped to the post.[40/] In the Phase I, Part A study, mature female rats were used. The Ergon device was allowed to operate continuously for 45 consecutive days, when twelve rodents were randomly selected from both treatment and control facilities. Each animal was then injected with either a saline solution or a saline solution containing ACTH. Sixty minutes after injection, the rodents were sacrificed. The same procedure was followed with the remaining rodents on the 46th day. Analyses were then made to determine whether there was evidence of stress in the treated rats. The data showed that the treated female rats had significantly greater adrenal weights and lower concentrations of white blood cells than the control rats. There were no significant differences in initial body weight, final body weight or percent change in body weight between the treated and control groups, indicating that the eating and drinking of the rats had not been affected. Nor was there any significant change in the corticosterone levels, which were significantly elevated by the ACTH injection in both groups.[41/] Dr. Pritchett considered the increase in adrenal weight indicated that the rats had been exposed to stressful conditions on the assumption that the adrenalin glands were still responsive to ACTH at the end of the test period, and that the decrease in white bloood cells also indicated exposure to stressful conditions.[42/]

40/ Tr. 487-488; Resp. Ex. 2A, 8B. The nearest rodent was about 5 inches from the device while the farthest rodent was 6 to 8 feet away. Tr. 488-489.

41/. Resp. Ex. 2A; Tr. 453-457.

42/ Tr. 453-455.

Phase I, Part B of the study was conducted with immature male rats. The rodents were again housed in individual cages in cage batteries with the Ergon device being attached to the corner post of the cage battery housing the treated rodents, and with treated and control animals being in separate rooms, all similar to what was done in Part A. Two separate experiments were conducted. In one experiment rodents were randomly selected from the control and treated groups and sacrificed 24 hours before the activation of the Ergon device and on days 14, 28, and 42 of the activation, and their adrenal glands were removed and weighed. In the other experiment, the animals were sacrificed after 41 or 42 days of treatment and analyzed with respect to their responsiveness to ACTH.[43/] The data showed that the adrenal glands of the treated rats decreased in size as they aged, and also that the treated rats injected with ACTH responded by the production of a lower amount of cortiscosterone than the control rats. Dr. Pritchett considered these two pieces of data as indication that animals had been chronically stressed causing them to be less responsive to ACTH.[44/]

The Phase II part of the study was intended to be conducted under simulated field conditions. Two identical structures were built, one for the control and one for the rodents treated with the Ergon device. The structures were erected on a concrete slab in open-sided sheds. They

43/ Tr. 460; Resp. Ex. 8B.

44/ Tr. 463; Resp. Ex. 8B. Dr. Pritchett explained that the apparent inconsistency between the increase in adrenal weights in the female rats in Part A and the decrease in adrenal weight in the male rats in Part B, could probably be accounted for by the differences in the sex and age of the rats used. The rats used in Part A were mature female rats while the rats used in Part B were immature male rats, and the adrenal gland in a female rat responds differently to ACTH than the male adrenal gland. Tr. 451, 511.

had plywood sides which were lined with concrete blocks to the height of the sides. Their dimensions were approximately 8 feet by 8 feet by 4 feet and they were filled with soil to the depth of 0.5 m (about 20 inches). A single Ergon device was installed in the soil at the center of each structure, but only the Ergon device for the treatment group was activated and remained in continuous operation for 40 days. At the end of the 40 day period, the rodents were sacrificed and analyzed for indications of stress.[45/]

The data for this test revealed no significant difference between control and treated rodents as far as adrenal weights or body weights were concerned, but did disclose a significantly lower plasma corticoid level. When the glands were subjected to in vitro treatment (incubated and then exposed to ACTH), the elevation of cortiscosterone production was found to be significantly lower in the treated groups at a level of 20 percent.[46/] Dr. Pritchett concluded from the fact that the treated rats had lower plasma corticoid levels and that their adrenal glands were less responsive to ACTH in the in vitro examination, that these rodents had been exposed to

45/ Tr. 467-469; 515.

46/ Tr. 469-471; Resp. Ex. 26. The 20 percent level is statistically a much less reliable indicator of whether the differences between the control and test groups are the result of inherent variations in the test subject having no connection with treatment with the Ergon device, rather than of treatment with the device. It means, in effect, that there is a 20 percent probability of error in rejecting the null hypothesis that there is no statistically significant difference between groups. See Tr. 272-275. Dr. Pritchett explained that he used the 20 percent level because the environmental conditions which might also influence the adrenal system could not be sufficiently controlled to permit statistical analysis at the more reliable 5 percent level. Tr. 474-476.

chronic stress.[47/]

The conclusion drawn by Dr. Pritchett from his testing was that the lack of responsiveness to ACTH observed in the Phase I, Part B and Phase II tests is a similar pattern to that pattern he observed in animals subject to chronic, intermittent, high intensity noise stress, and that the data "is a fairly strong indicator. . .that exposure of these animals to this Ergon Pest Control System does constitute a physiological stressor."[48/]

The Ergon device in Dr. Pritchett's tests was installed as recommended by Respondent's distributor, Rodent Ridder, Inc., so it can be assumed that unlike Respondent's criticism of the EPA's tests, the device was installed and monitored in a manner which Respondent regarded as making most effective use of the device under the test conditions, including whatever wiring of the repeller bar was considered desirable.[49/] Also, there appears to have been no problem with the rodents being insulated from the device such as Respondent claimed was presented by housing the test rodents in a wooden building. Even though the tests were conducted under what could presumably be considered optimum conditions, however, there are significant questions about what the tests actually show with respect to the effectiveness of the Ergon device.

47/ Tr. 470-471.

48/ Tr. 471.

49/ Tr. 466, 488; Resp. Ex. 2A.

One factor to be noted is that in none of Dr. Pritchett's tests was the device observed to have any effect on the eating or drinking of the rodents.[50/] For these parameters the results were consistent with the results of the Beltsville test.

Another factor to be considered is that in the Phase I tests the farthest away a rodent was from the device was 6 to 8 feet, while in the Phase II simulated field test no rodent could have been more than four feet from the device. These distances fall far short of the 2 1/2 acres represented in the sales literature as being the effective range of the device.[51/]

Finally, assuming that the device can act as a stressing agent within the short range that it was tested, it is not really possible to gauge whether the stress is of a magnitude to cause the rodents to avoid or leave an area within range of the device. Dr. Pritchett, himself, recognized that animals can adapt to even chronic stress. Even his studies of the effects of noise stress show the fact that rodents are stressed does not necessarily mean that they will leave the area.[52/] The mildness of any

50/ None of Dr. Pritchett's tests showed significant body weight differences between the test and control animals. This presumably indicated that the test rodents were consuming food and drinking water at a normal rate during the test. See Tr. 453. No measurements were made in Dr. Pritchett's tests of the effect of the Ergon device on breeding by the rodents.

51/ See EPA Ex. 6.

52/ See Tr. 530-532.

stress caused by the Ergon device would seem to be evidenced by the fact that it did not appear to affect the eating or drinking of the test rodents.

The limitations of his tests in demonstrating the effectiveness of the Ergon device are revealed in the following testimony of Dr. Pritchett:

JUDGE PERLMAN: Are you saying you assumed for the purposes of your study that what the manufacturer told you that it did it did?

DR. PRITCHETT: Right. I had no reason to disbelieve him.

JUDGE PERLMAN: So that statement that you made that you are supplying perhaps biological bases for the manufacturer's claim, which claims you just assumed were so because you were told that was the case.

THE WITNESS: That is true.

JUDGE PERLMAN: And you have no basis to know whether that is so or not.

THE WITNESS: Whether or not it works out in the field?

JUDGE PERLMAN: Right.

THE WITNESS: We have never tested that.

JUDGE PERLMAN: You are just saying if it works, if the manufacturer's claims are as stated, this is some evidence to show why that is so.

THE WITNESS: This provides a possible biological basis.[53/]

53/ Tr. 533-534.

It is, of course, recognized that the testing done at Beltsville is also of limited value and that Dr. Pritchett's tests have a claim to greater reliability since the Ergon device itself was used in the tests and was installed in a manner suitable to Respondent, while the EPA's tests had been done with a comparable device which Respondent contends was not properly installed. But the information disclosed in Dr. Pritchett's tests about the device subjecting rodents to some kind of stress must be weighed against evidence disclosed in the EPA's studies and confirmed by Respondent's own studies that the device emits a very weak electromagnetic field whose strength at a distance of 10 feet is considerably below the strength of the earth's magnetic field, and that whatever possible stress was detected in Dr. Pritchett's tests was not great enough to affect the eating and drinking of the rodents even when they were in close proximity to the device.[54/] In view of the EPA's evidence demonstrating the lack of any significant effect on the rodents or their behavior, it must be shown that the stress is great enough to control or repel the rodents. This was not shown in Dr. Pritchett's tests.

54/ Nor can the EPA's evidence that the device does not affect the breeding of rodents be ignored in view of the fact that Respondent produced no reliable evidence to the contrary. Respondent did have a controlled study made by the Sinclair Research Farm of the University of Missouri to determine the effect of the device on the reproduction and growth rate of caged rats and mice. Resp. Ex. 16A. The study, however, yielded inconclusive data. See Mr. Jacob's analysis in EPA Ex. 16 and Tr. 281-290. Respondent has not questioned Mr. Jacob's analysis and does not appear to rely on this particular study in its brief.

In addition to its controlled laboratory tests, Respondent also had a study made by the Sinclair Research Farm at the University of Missouri which consisted of visually observing the effects of the device on the wild rodent population infesting the barns at the farm.[55/] It was contended that the use of poisons had not decreased the rodent population to any extent. The study consisted of installing the Ergon device in nine barns. The devices were activated on December 4, 1979, and between that date and January 11, 1980, all poison was removed from the barns. After that date, the poison was put back in the barns and used in conjunction with the device.[56/]

Mr. Glendenning from the Sinclair Research Farm, who participated in the study, reported that during the period from December 4, 1979, to January 11, 1980, when the device was operating without poison being also used, he noticed a great increase in rodent activity in the barns, and apparently an increase in the number of rats trapped. After Janury 11, 1980, when poison was put back in the barns, visible signs of the presence of rodents decreased greatly. Mr. Glendenning reported that after four months of using the device and poison together, "We still see mice in all our barns, but not the numbers that we had before the poison was put out. . . . We also have not seen much damage to barn insulation or feed since the devices were installed." He further reported that no

55/ Resp. Ex. 16A; Tr. 538-569.

56/ Tr. 551-552.

rats have been seen since the devices were installed and the rats were trapped.[57/]

As to the reliability of this study, it is to be noted that the study records only the viewer's subjective interpretation of what he observed. There were no quantitative measurements made of rodent populations in the barns prior to, during, or after the Ergon device was used either alone or in conjunction with rodent poison and traps.[58/] Also, the use of rodent poison and rat traps are recognized ways of dealing with rodent infestations and there were no quantitative measurements made to determine to what extent they and not the device were, in fact, responsible for any decrease in the rodent population.[59/] Finally, there was no attempt to isolate or measure the effects of other variables which could influence the rodent population, such as, for example, the weather.[60/] In conclusion,

57/ Resp. Ex. 16A, 17; Tr. 551-553.

58/ The EPA's expert, Mr. Jacobs, described several ways in which the size of the rodent population could have been measured, such as the live trapping of animals, or setting up an experimental food station prior to actual control effort to determine the feeding levels of the population, or setting up areas to measure rodent traffic either through counting footprints, or by use of a photocell, or by analysis of rodent droppings in grided areas. Tr. 293.

59/ For example, Mr. Glendenning stated that two installations of the device were ground-barn installations, and in these cases the device drove rats out of the ground and into the barn, where they were trapped. Tr. 553. This would seem to imply that the Ergon device did not repel rats from the building even though it was represented as eliminating and controlling rodent infestations in barns as well as in the field. EPA Ex. 6.

60/ See Tr. 475-476. As Dr. Jacobs explained, the greater rat activity inside the barns after the device was first activated could have been caused by the tendency of the rats to escape from the cold. Tr. 293.

therefore, it is found that the visual observation study performed by the Sinclair Research Farm of the University of Missouri is entitled to little weight as proof of the Ergon device's effectiveness in controlling rodents.

The same reasons which make the Sinclair Research Farm's visual observations unreliable would seem to apply to an even greater degree to the testimonials from satisfied users. There is simply no basis for determining the accuracy of either the witness' perception as to what had actually happened to the rodent population, or his judgment that what did occur could be attributed to the device rather than to some other factor.

It is concluded, then, that the Ergon device is ineffective in eliminating or controlling rodent infestations.[61/]

The only charge of the complaint which Respondent has really disputed in this case is whether the Ergon device is effective in eliminating or controlling rodents as represented in the sales literature which accompanied Respondent's shipments of the device. If it is not, Respondent has not

61/ It is not necessary to consider the EPA's testing done by the University of California at Davis with another Amigo device, since unlike the Ergon device, it had only two coils and no repeller bar. See EPA brief at 16.

questioned that Respondent has violated FIFRA, Section 12(a)(1)(F) by selling and shipping a device which is misbranded.[62/]

Accordingly, it is found that Respondent has violated FIFRA, Section 12(a)(1)(F), by selling and shipping a device which is misbranded.

62/ FIFRA, Section 12(a)(1)(F) provides in pertinent part that, "/I/t shall be unlawful for any person in any state to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment. . .to any person. . . any device which is misbranded." Although Respondent denied in its answer that the Ergon Pest Control System was a "device," it has not pursued the matter in its brief. As an "instrument or contrivance" which is admittedly intended for destroying or repelling rodents, the Ergon Pest Control System is clearly a "device" within the meaning of FIFRA, Section 2(h) and pursuant to Regulation of the EPA, 40 CFR 162.15, has been made subject to the misbranding provisions of FIFRA. Under FIFRA, Section 2(q), 7 U.S.C. 136b(q), a device is misbranded "if its labeling bears any statement. . .relative thereto. . .which is false or misleading in any particular." "Labelling" is defined by FIFRA, Section 2(p)(2), 7 U.S.C. 136b(p)(2), to include "written, printed or graphic matter. . .accompanying the. . .device at any time." Consequently, the sales literature packaged by Respondent with the devices it shipped on consignment to its distributor constitutes labelling under FIFRA. See Supra, Findings of Fact 2 and 3.

The Assessed Penalty

The assessment of penalties for violation of FIFRA are authorized by Section 14, 7 U.S.C. 136 l, which provides in pertinent part, as follows:

> (a) Civil Penalties. --
> "(1) In General. -- Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.
>
> * * *
>
> "(4) Determination of Penalty. -- In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. . . ."

The EPA has issued guidelines for the assessment of civil penalties which are intended to take into account the statutory standards in determining the penalty appropriate to the violation found. 39 Fed. Reg. 27711 (July 31, 1974). Complainant has proposed a penalty of $10,000, in accordance with the maximum statutory penalty of $5,000 recommended for labelling violations consisting of inadequate directions for use which render the product totally inefficacious. 39 Fed. Reg. at 27714. Contending that each of the 4,500 units sold would constitute a violation, the EPA asserts that $10,000, the penalty for two violation, is proper. The penalty seems appropriate, and Respondent has presented no evidence to the contrary. Accordingly, a $10,000 penalty is assessed.

Final Order [63/]

Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, Section 14(a)(1), (7 U.S.C. 136 l(a)(1)), a civil penalty of $10,000 is assessed against Respondent VRP Corporation for violations of the Act found herein.

Payment of the full amount of the civil penalty assessed shall be made within sixty (60) days of the service of the final order upon Respondent by forwarding to the Regional Hearing Clerk a cashier's check or certified check payable to the Treasurer, United States of America.

Gerald Harwood
Gerald Harwood
Administrative Law Judge

Dated: December 28, 1981

63/ Unless an appeal is taken pursuant to the Rules of Practice, 40 CFR 22.30, or the Administrator elects to review this decision on her own motion, the INitial Decision shall become the final order of the Administrator. See 40 CFR 22.27(c).