

6/27/91

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF THE ADMINISTRATIVE LAW JUDGES

BEFORE THE ADMINISTRATOR **RECEIVED**

JUL 02 1991

EPA/ORD

Regional Hearing Clerk

In The Matter of

:
:
:
:
:
:
:
:
:
:
:

IMPEX INDUSTRIES, INC.

Docket Number:
FIFRA-I-84-1048

Respondent

Federal Insecticide, Fungicid, and Rodenticide Act, (FIFRA) 7 U.S.C. §136 et seq: ultrasound units which did not control or eliminate rodents to the degree or with the consistency stated on the labeling were "misbranded" within the meaning of the Act.

APPEARANCES:

Michael Walker, Esq., Legal Branch, United States Environmental Protection Agency, 401 M Street S.W., Washington, D. C. 20460, for complainant. Robert W. Pittman, Jr., Esq., United States Environmental Protection Agency, 401 M Street S.W., Washington, D.C., 20460 on brief for the government.

Edward A. Sokoloff, Esq., 20 Nason Street, Maynard, Massachusetts 01754, for respondent.

BEFORE; J. F. Greene
Administrative Law Judge

This matter arises under 7 U. S. C. §136, et seq., the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (hereafter "FIFRA" or "the Act"), and the regulations promulgated thereunder at 40 C.F.R. Part 162. In this civil action, the United States Environmental Protection Agency (hereafter "complainant" or "EPA") seeks assessment of civil penalties against respondent Impex Industries for allegedly misbranding ultrasonic devices marketed to control rodents in violation of 7 U.S.C. §136(a)(1).¹

Counts I and II of the amended complaint of June 8, 1987, charge that on or about December 3, 1980 and July 27, 1982, respondent held for sale the "Sonitron Model C" and "Sonitron Model Super C" products, respectively, as rodent control devices² within the meaning of 7 U.S.C. 136(h), which were "misbranded" within the

¹ FIFRA §2(q)(1)(A), 7 U.S.C. §136(q)(1)(A), provides that a "pesticide is misbranded if (A) its labeling bears any statement, design, or graphic design relative thereto or to its ingredients which is false or misleading in any particular." Section 162.15 of the regulations brings a "device" within the purview of the Act. 40 C.F.R. §162.15.

² Respondent asserts that the Sonitron units are not "devices" and are, therefore, not subject to the labeling provisions of the Act. The Act defines "device" at section 2 (h), 7 U.S.C. § 136(h), as

. . . . any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

Since it is clear that the Sonitron units are instruments or contrivances intended for repelling or mitigating a pest, it will be held that they are "devices" within the meaning of the Act and are subject to the labeling provisions of the Act.

meaning of that term as it applies to pesticides, 7 U.S.C. §136(q), and devices, 40 C.F.R. §162.15, because the labeling made claims which complainant further alleges are false and misleading. It is unlawful, under the provisions of section 136(j)(1)(F) of the Act for "any person in any State to . . . hold for sale . . . any device which is misbranded." Specifically, the complaint alleges that the Sonitron Model C and Sonitron Model Super C are ineffective for rodent control.³ Respondent discontinued the sale of the Sonitron Model C on December 3, 1980.⁴

Respondent's position is that the Sonitron Model Super C units were not held for sale, but were given to the EPA as experimental units. Nevertheless, respondent states that the Model C and Super C are effective for rodent control and it has submitted documentary and oral evidence in support of this position. Respondent asserts that the use of its products, in conjunction with conventional rodent control methods such as baits, traps, sanitation, and closing holes, will provide effective rodent control. Respondent further maintains that tests conducted by complainant's expert Dr. Steven Shumake, upon which complainant relies, are defective and the test results are inaccurate and unreliable. Despite the

³ Paragraphs 6 and 7 of Count I of the complaint, and paragraphs 15 and 16 of Count II.

⁴ Paragraph 11 of Count I of the complaint. The term "labeling," as defined at 7 U.S.C. §1369(p)(2), FIFRA §2(p)(2) means "all labels and all written, printed, or graphic matter - (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device"

alleged defects in the tests, however, respondent claims that the results establish the effectiveness of the Sonitron units for rodent control.

DISCUSSION

The voluminous record in this matter includes a substantial amount of documentary evidence as well as the testimony of several experts on behalf of both parties. The issues presented for decision are as follows: (1) whether the Sonitron Model Super C was given to EPA as an "experimental" unit; (2) whether the government suspected a violation of the Act at the time the units were received; (3) whether this administrative action was lawfully commenced; and (4) whether the Sonitron units are "misbranded" within the meaning of the Act and regulations.

I.

Whether the Sonitron Super C Units Received by the Government are Experimental.

Respondent argues that the Sonitron Model Super C devices received by EPA on July 27, 1982, were not held or offered for sale, but were experimental units. However, the record discloses that respondent's president signed an EPA form [CX 9] which states that the Super C devices "were obtained from pesticides or devices that were packaged, labeled, and released for shipment." Respondent's president testified that he probably read the request

form before signing it, but that he believed that he "was just signing because [the EPA official, Mr. Kalayjian] wanted some kind of receipt and this only implied a receipt for him." [TR 1899-1902]

Mr. Gerald Stubbs, an EPA case development officer and wildlife biologist [TR 458] testified that if the Super C units had been experimental, they would have been rejected because the agency does not accept experimental units. [TR 3392] Mr. Kalayjian picked up the units on July, 1982. He was not advised by respondent's president or by any employee that the units were experimental. [TR 3563]

The testimony of Stubbs and Kalayjian is credible. The foregoing evidence establishes that the Super C units received by the government on July 27, 1982, were not experimental. The form signed by respondent's president is unambiguous. It must be held that, having signed the form, he is presumed to have known its contents.

II.

Whether EPA Suspected a Violation of the Act At the Time the Units were Collected.

Respondent asserts that, at the time of EPA's visits on December 3, 1980 and July 27, 1982, a violation of the Act was suspected but EPA failed to notify Impex. Subsection 136(g)(a)(2) states, in part, as follows:

- (2) Before undertaking such inspection, the (agency) officers or employees must present

. . . a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. 7 U.S.C. 136(g)(a)(2).

Complainant asserts that it did not suspect a violation of the Act at the time the Sonitron units were received. Indeed, respondent was notified that a violation of the Act was not suspected, but that the units were needed for efficacy testing.

In support of its assertions, respondent states that as early as 1976, Mr. Stubbs had received complaints about the claims made for ultrasonics. Mr. Steve Palmateer subsequently initiated testing of the Sonitron Model C on January 10, 1978 but, these tests were never completed. Stubbs testified that a letter dated January 22, 1980, to Edward Rich, which Stubbs co-authored, was not intended "to point out the fact [that] ultrasound, in general, doesn't work." Stubbs stated that, at the time, he felt that some rodents would continue to feed notwithstanding the presence of ultrasound but that he "suspected there might be a frequency or a decibel that might work on rodents." Moreover, Stubbs denied that respondent had been targeted in the government's efficacy testing since respondent had asked Stubbs to test its devices in 1980 and "[a]t that time [Stubbs] felt that ultrasound was effective against rodents to some extent and not against anything else.

At the initial stages of his testing in 1980, complainant's expert Dr. Steven Shumake states that Stubbs told him, "If you find repellent effects that are strong and significant, consistent, so be it. Write your report accurately and do the best job you can."

Indeed, Shumake recalls that, at the time, "the book was still open" as to the effectiveness of ultrasound. [TR 617-8] In 1982, Dr. Shumake submitted a request for additional Sonitron units to be used in field studies. There was minimal communication between Mr. Stubbs and Dr. Shumake regarding the testing. Mr. Stubbs first suspected that respondent had violated the labeling laws after he saw the initial test report.

It is determined that the record contains substantial evidence, including credible testimony from Mr. Stubbs and Dr. Shumake, to support a finding that complainant did not suspect a violation of the Act at the time the units were obtained.

III.

Whether This Action Was Lawfully Commenced.

Respondent argues that the EPA Administrator is without authority to bring an action in this case, citing 7 U.S.C. §136(a)(c) which reads, in pertinent part:

[I]f in the opinion of the Administrator it appears that the provisions of this subchapter have been violated by such person, then the Administrator shall certify the facts to the Attorney General, with a copy of the results of the analysis or the examination of such pesticide for the institution of a . . . civil proceeding under section 136(1)(a) of this title, when the Administrator determines that such action will be sufficient to effectuate the purposes of this subchapter.

7 U.S.C. §136(g)(c) (emphasis added). Complainant urges that the foregoing provision is discretionary with the Administrator and that this proceeding was properly commenced under subsection

136(1)(a) without the involvement of the Attorney General.
Subsection 136(1)(a) provides as follows:

Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this subchapter may be assessed a civil penalty by the Administrator of not more than \$5,000 for each offense.

7 U.S.C. §136(1)(a)(1). Subsection 136(1)(a)(5) provides for a matter to be referred to the Attorney General "[i]n the case of inability to collect such civil penalty as the Administrator may determine" 7 U.S.C. 136(1)(a)(5).

It is apparent from the foregoing that the Administrator has discretion to determine whether to refer a matter to the Attorney General, in which case the facts of the case must be certified. The Attorney General is not a necessary party to an administrative proceeding. The Attorney General's authorization lies in bringing an enforcement action in federal district court to enforce the collection of civil penalties assessed. Accordingly, it is determined that this proceeding was properly commenced.

IV.

Whether The Sonitron Units Are Misbranded.

Literature which accompanies the Model C and Super C ⁵ states that "Impex Industries presents the Sonitron System for sonitizing

⁵ Robert Kilayjian testified that respondent's president gave him literature for the Model C at the time he received the Super C units on July 27, 1982, and stated that the literature for the Super C had not been completed. However, Kilayjian recalls that respondent's president told him that the Model C literature would be adequate for the Super C units. Kilayjian's testimony is credible and, therefore, it is determined that the Model C literature will also serve as the Super C literature in this case.

the total system for proven rodent control utilizing the remarkable Sonitron ultrasonic electronic devices with a regular program of peripheral trapping and/or baiting" ⁶ and "Sonitizing is highly effective wherever rodents are to be controlled." Respondent asserts that "sonitizing" includes the use of baits, traps, sanitation, closing holes, and/or glueboards in conjunction with ultrasound such that the combination of these methods does in fact provide "highly effective" and "proven" rodent control. Complainant, on the other hand, argues that the use of ultrasound must, in and of itself, provide a significant contribution to the pest control program. Otherwise, the statement that "sonitizing is highly effective" or that sonitizing provides "proven control" is misleading.

Statements contained within a product's literature must be read reasonably (i.e. harmoniously and consistently) with other statements in the literature and with the purpose of the product as determined by reasonable consumer expectations. The Sonitron devices are intended to repel rodents by ultra higher frequency sound. Complainant's experts Drs. Howard, Jacobs, and Shumake consider conventional methods of rodent control to be, in and of

⁶ Respondent asserts that it was not given notice that the statement regarding "proven control" was challenged as false and misleading because the complaint inaccurately states that "[Sonitron provides] proven rodent control." However, the complainant's version of the labeling is not so divergent from the actual statement so as to leave respondent without notice.

themselves, highly effective. Indeed, Dr. Walter Howard testified that he could not conceive of failure to control rodents where conventional methods are properly utilized. [TR 861]

The labeling which accompanies the Sonitron units states the following:

The objective is to provide protection in the area where rodents are present. This is done by SONITIZING your premises. We accomplish this with the strategic placement of SONITRONS-- sophisticated ultrasonic devices that send out powerful sound waves above 90 decibels.

From the foregoing, a consumer would reasonably expect that the Sonitron is essential to the "sonitizing" program. Furthermore, the labeling also states that "[m]any users of ultrasonic units have successfully cleared the area of rodents without a much more complicated approach than by simply plugging in these units". Consequently, it is essential to establish the effectiveness of the ultrasonic units without the use of other methods of rodent control.

In support of its position that the Sonitron units are effective in rodent control, respondent submitted a substantial quantity of oral and documentary evidence. The testimony of Mr. Farook Taufiq, Vice President of Prince Macaroni Company, as well as the testimony of Mr. Robert Conner and Mr. Robert Culver provide credible reports of rodent control, in that it is clear they believed that their control efforts, including the use of Sonitron units, were successful. However, their testimony is of less probative value for two reasons: baits, traps, sanitation, closing holes, and/or glueboards were employed in conjunction with the

ultrasound units they used, and, even more important, there is no data resulting from a program of consistent monitoring of these sites. As a result, there is no objective way to measure the consistency, reliability, and accuracy of observations.

Likewise, numerous consumer reports, surveys, testimonials offered by the respondent, though credible, are entitled to little weight as they are inherently subjective, less accurate, and less reliable. Such evidence does not rise to the level of a scientific study. The reports are not accompanied by controls and objective data derived from a regular program of monitoring from which reasonable conclusions regarding the efficacy of ultrasound may be drawn. Moreover, the consumer reports involve the concomitant use of ultrasound and baits, traps, sanitation, closing holes, and/or glueboards, consequently, any observed success in rodent control cannot be contributed to ultrasonics.⁷

Dr. Charles Mampe utilized ultrasonic units at a food warehouse in Carlstadt, New Jersey, a grass seed blending and packaging operation in Hoboken, New Jersey, and a food distribution warehouse in Fairfax, Virginia. In all three situations, Dr. Mampe instituted conventional rodent control methods in addition to

⁷ This evidence includes the following: the Woolworth Department Store in Warwick, Rhode Island; the Marriott Hotel in Providence, Rhode Island; Colfax Corporation in Pawtucket, Rhode Island; Valle's Steak House in Hartford, Connecticut; the U. S. Post office in Providence, Rhode Island; Charlesgate Nursing Home in Providence, Rhode Island; Rhode Island Port Authority in Quansett Point, Rhode Island; Rhode Island Hospital at Providence, Rhode Island; Johnston's Dressed Beef; the Coast Guard Restaurant at Naragansett, Rhode Island; and over 200 miscellaneous installations of Sonitron devices by Dr. Charles Mampe.

ultrasound and concludes that "the two used in conjunction can achieve a high level of control whereas neither one its own accomplishes a measurable level of control." [TR 2067-68]. Specifically, Dr. Mampe determined that the ultrasound interrupted the movement patterns of the rodents. The sites were not well monitored, no data was recorded, and there is no objective measure of the effectiveness of ultrasound used alone. The assertion that ultrasound merely disrupts the movement of rodents does not afford a sufficient basis upon which to find that the Sonitron is an integral part of a "highly effective" and "proven" rodent control program.

The examinations of rodent behavior by Drs. Jackson and McCartney at the Pritts Grain Mill in Mount Pleasant, Pennsylvania, the Skokot Dairy Farm in Smithton, Pennsylvania, the Adam Baum Egg Farm in New York State, the General Nutrition Food Stores in Boston, Massachusetts, and the Super Value store in Des Moines, Iowa, were conducted under contract with respondent and are offered by the respondent to demonstrate the efficacy of ultrasound. However, according to Dr. Jackson, observations which took place at these sites are insufficient to demonstrate the efficacy of ultrasound.

Drs. Jackson and McCartney state that their data collection and resulting conclusions do not rise to the level of a scientific "study," and involve a lower "level of precision" than Dr. Shumake's examinations and analysis at Building 3A and the pumphouses. Indeed, Drs. Jackson and McCartney concede that their

testing involved only a series of observations from which they concluded that ultrasound disturbed the movement patterns of rodents. Dr. McCartney questions the statement that the Sonitron "is highly effective wherever rodents are to be controlled", noting that the term "wherever" can encompass many places. Finally, other methods of rodent control were used in conjunction with ultrasound, thereby making it impossible to determine whether the ultrasound was itself effective.

Likewise, Drs. Howard and Jacobs believed that the observations of Drs. Jackson and McCartney were not of scientific quality, since the protocol and data collection at the foregoing sites were inadequate. In particular, Dr. Jacobs states that the egg farm study was "very sloppily organized" and was "not good science". Documentary evidence underlying the egg farm examination reveals irregularly scheduled observations, unit malfunctioning, and lack of controls at the site.

The observations at the Nutrition Stores likewise contained insufficient controls and inadequate data collection. The report states that "periodic inspections and observations" were made by an employee of Waltham Chemical Company. At the Boylston Street store, it was noted that "when Talon was exposed, it was readily accepted; and the mouse problem ceased." At the Temple Street store, significant rodent activity continued in the basement and numerous complications evolved regarding the Sonitron units, including that the electricity was turned off by the employees at various times during the observation period. Dr. Jackson asserts

that, due to an ultrasound field, rodent activity at a peanut butter machine at the Boylston Street store essentially stopped. However, as previously noted, the use of bait and premises sanitation compromises the conclusion that interruption of rodent activity was due to ultrasound.

At the dairy barn, Dr. McCartney collected data at 4:30 a.m. every three days and then removed the tracking patches before cows were allowed inside the building. Because rodents were covered with water and "other matter", McCartney could not count tracking activity; rather he employed the less precise measure of reviewing the total area disturbed on each patch. Further, cats were present in the building and baits were utilized. Accordingly, the dairy barn observations did not have sufficient controls to constitute a scientific study.

The Pritts grain mill basement was covered with flour. Tracking activity indicated heavy rodent infestation. Two types of bait were used in the basement which, according to McCartney, "were not being accepted." [Tr. 1542]. McCartney did not conduct any statistical analysis of his data because he felt that it was not necessary to answer the question which he "was being told to answer, and that was what, if any, were the effects of ultrasound on the movement patterns of Norway rats in a grain mill." [Tr. 1651] Moreover, concern was expressed about the sounds of conveyor belts and human disturbances at the mill. It is

determined that the Pritts grain mill observations do not rise to the level of a scientific study and are, therefore, entitled to little probative value.

Finally, at the Super Value store, Drs. Jacobs and Jackson note that the units were mounted too high to be effective. According to Dr. Jacobs, the store provided only "an account with recommendations". Indeed, a review of the documentary evidence underlying the Super Value store confirms that the units were mounted too high to be effective and there is no showing that the units were lowered. Most of the evidence in the exhibit consists of letters between Mr. Scalingi and Super Value management regarding the sale and repair of units. There is no consistent monitoring of rodent activity at the Super Value store, -- merely employee reports of rodents caught in traps.

The examinations at the egg farm, grain mill, dairy farm, nutrition stores, and Super Value store did not have sufficient controls and were not well monitored. Moreover, all of the sites involved the use of ultrasound in conjunction with other methods of control. A review of the oral and documentary evidence demonstrates that the examinations conducted by Drs. Jackson and McCartney are not of scientific quality, involve a combination of rodent control methods, and indicate, at most, that ultrasound may cause a disruption in the movement patterns of the rodents for an uncertain duration. Consequently, these examinations clearly fall short of establishing that ultrasound is "effective" and "proven" as an essential part of an integrated pest control program.

Studies conducted by Dr. Steven Shumake at Building 3A⁸ and the pumphouses do, on the other hand, demonstrate the limited and inconsistent effect of ultrasound upon rodents. Respondent asserts that the protocol used at Building 3A was developed by persons without expertise. However, the record shows that the protocol was designed by Kenneth Lavoie and was subsequently reviewed and approved by Dr. Shumake, qualified as an expert in experimental psychology. Moreover, Dr. Jacobs, qualified as an expert in protocol, reviewed the test designs and data collection methods for Building 3A and the pumphouses prior to the studies and found them to be reasonable and adequate. Likewise, Dr. Howard approved of the test designs for Building 3A and the pumphouses. Dr. Jackson notes that Shumake's methods of testing and data collection are more precise than those which he employed in his examinations. As a result, substantial evidence of record in this matter supports a finding that the protocols underlying Dr. Shumake's studies are adequate.⁹

⁸ Respondent asserts that the Sonitron Model C unit actually emitted "substantially greater than 90 decibels", yet failed to state what this higher reading was. [See note 8, continued in the In Camera portion of this decision]. It is determined that the unit at Building 3A emitted 90 decibels at 11 feet.

⁹ Respondent notes that Dr. Shumake failed to use two-way glass or a videotape during the testing at Building 3A and urges that this failure compromised his data. However, no test protocol experts of record state that the lack of two-way glass or videotape invalidated the data. On the contrary, Drs. Howard, McCartney, Jacobs, and Jackson testified that the absence of a videotape or two-way glass did not render the study invalid. Dr. Shumake reported that at the beginning of the study a videotape was used, but it did not prove helpful. From the foregoing, it is determined that the test protocol is not defective for failure to use two-way glass or videotape.

Dr. Shumake decided that, although "[t]he most frequently recommended use for the Sonitron unit is in conjunction with baiting and trapping", his testing should be designed to reveal the effects of ultrasound without the use of other methods of control. This is because the labeling of the units clearly promises that, in some instances, ultrasonics is all that is required to clear an area of rodents permanently.

A Sonitron Model C, Sample Number 202002, was installed in a simulated test structure at Building 3A on June 21, 1982, where it remained until October 7, 1982. 750 square feet of space at Building 3A where the trials were conducted "served to measure efficacy and evaluate the procedures and measurement techniques before field trials were initiated". Although it was not costly to use Building 3A, Dr. Shumake stated that he would not have selected any other building even if budget for testing been larger, because Building 3A was sufficiently large and isolated to provide the basis for accurate results as to the effects of ultrasound.

Building 3A was divided into an east room, a west room, and a central (or "harborage") area. Twelve Norway rats (six male and six female) were used for testing in Replication 1. A different set of twelve Norway rats (six male, six female) were used in Replication 2. The Sonitron unit was mounted in the east room for Period 1 of each replication and in the west room for Period 2 of each replication. Dr. Shumake states that the "second period . . . was designed to insure that extraneous factors such as temperature, noise, odors, and floor texture would not interfere

with the assessment of the device." A total of 30-32 packets of oat groats were placed in both the Sonitron and control rooms, and the central area contained water, shelter, and enough lab chow to sustain the population throughout the study. Baseline activity was measured for each period. Dr. Shumake states that "[t]o minimize human disturbance, data were collected on alternating 3- and 4-day intervals (Mondays and Thursdays)".

Statistical analysis of photocell breaks and food consumption reveals that ultrasound would not contribute effectively to an integrated rodent control program. Dr. Shumake states that "a consistent repellency effect for the Sonitron device was not indicated Neither did we find a consistent increase in consumption over baseline levels for the control room area when this device was activated." Indeed, the data evidences effects which are "undifferentiated" after the first week.

Dr. Shumake received two Sonitron Model Super C units on July 27, 1982, Sample Numbers 226776A and 226776B. These units were used in field tests from July 6, 1982 to October 5, 1982. They were installed in a wood irrigation equipment storage building and metal grain storage building which "were surveyed for at least 2 weeks for rodent tracks" and "[a]s later confirmed by snap traps, both buildings were infested with house mice" All three Sonitron units were then tested at isolated pumphouses from June 14, 1983 until August 16, 1983. Dr. Shumake states that the foregoing sites were chosen for testing because there was evidence of rodent activity in each of the buildings, and because the

buildings were isolated. Tracking tiles dusted with baking flour were placed at certain locations near the walls. Again, baseline activity was measured and data collected every three to four days in order to keep human disturbance at a minimum.

Chi-square analysis of licking and tracking activity at the pumphouse field sites indicated that "the test sample devices produced no statistically reliable effects at any of the pumphouse sites." Indeed, no effects were noted at the metal grain storage and wood irrigation equipment storage building. In sum, Dr. Shumake reported the following:

Such partial, temporary, and unreliable effects tend to raise serious doubts about the claim of improved efficacy of traditional control methods . . . when used in conjunction with Sonitron units. Professional pest control personnel have known for years that dark, quiet corners and peripheral areas in a structure are the best candidate loci for bait, trap, and glueboard placement.

Dr. Shumake concluded that the Sonitron units do not effectively repel or control rodents. Indeed, he testified that the use of ultrasound would not increase the effectiveness of an integrated rodent control program.

Respondent argues that Dr. Shumake's studies are compromised for the following reasons: food in the harborage area was not preferred; food was consumed in the harborage area; the rodents removed food packets closest to the exit ports of the Sonitron room; dominance, stress, and other behavioral factors were not taken into consideration; and the birthrate of the rodents in Building 3A was low.

Taking first the argument that food in the harborage area was not preferred to the food in the Sonitron room, the record shows that this is not a defect in protocol or data collection. Rather, it demonstrates the ineffectiveness of the ultrasound that rodents would seek "preferred" food in the Sonitron room. Indeed, such a position militates against the possibility of success with "sonitizing," which is premised upon the idea that the Sonitron unit will drive rodents away from areas of maximum infestation to baits, traps, or glueboards placed in the peripheral areas of a building. A review of the test report reveals that both the control room and Sonitron room contained 30-32 small paper packets of rolled oat groats. In the central area, enough lab chow was available to sustain the rodents during the test. The rodents had ample opportunity to feed on the "preferred" food in the control room or to eat lab chow in the central harborage area. Accordingly, the fact that the rodents may have "preferred" oat groats in the Sonitron room does not compromise the test.

Moreover, the fact that food packets could be removed and possibly eaten in the central area does not render the test results invalid. The central area contained food, water, and shelter. The record establishes that rodents prefer safe, dark, peripheral areas and that they feel most secure near their nests. Packets were removed from both the Sonitron and control rooms. It is reasonable that the rodents would have eaten in the central area, with or without the presence of ultrasound. Moreover, credible expert testimony of record supports a finding that those rodents which

learned how to remove the food packets would have done so notwithstanding the presence of ultrasound. Consequently, respondent's argument that the test was compromised because food packets could be removed and food may have been consumed in the central area is not convincing.

Failure to consider dominance, stress, and other behavior during the testing does not invalidate the studies. Respondent asserts that it is possible that dominant rats controlled food sources and chased other rats so that "the photocell measure of activity and the accuracy of the food consumption data would be problematic." There is no evidence in the record which indicates that dominance activity adversely affected any of the test results. On the other hand, the record supports a finding that social hierarchies form naturally within rodent populations and, therefore, the possibility that the rodents formed a social hierarchy during the tests does not result in an unacceptable bias in the data.

According to Dr. Jackson, rodents will exhibit "darting" behavior upon their first exposure to ultrasound. However, after a short time the rodents become acclimated to the presence of ultrasound and feed in its presence with "minimal reaction" to it. Dr. Shumake's report states that the photocell data in the Sonitron room never showed less than 500 counts per day throughout the test period and, at times, it exceeded 2,000 counts per day. The possibility that photocell data was increased due to dominance or "darting" activity does not rebut the observations that the rodents

continued to enter the Sonitron room and food was consumed in that room throughout the test period. Rather, it further demonstrates the inconsistent and minimal impact of ultrasound on the rodents.

Respondent notes that one litter of rodents was born, thus indicating "atypical" behavior of a free-living Norway rat population. Dr. Shumake states that two litters would be expected during the test period. Dr. McCartney believed one litter would be normal. Since there is no documentary evidence or expert testimony of record which attributes the birthrate to the presence of ultrasound, it will be found that the birthrate in this case does not constitute a defect in protocol or data collection at Building 3A, or render the test results unreliable.

Respondent argues that Dr. Shumake's tests are invalid because no field tests were conducted on Norway rates, the Sonitron Model Super C was not tested in Building 3A, there were behavioral differences between the populations of rodents at Building 3A, and the data in Period 2 of each replication is invalid. The Norway rats were studied under simulated field conditions, with adequate protocol and data collection techniques. Dr. Shumake's tests reveal short term, inconsistent effects of ultrasound upon the rodents at both the simulated field site as well as the actual field sites. Moreover, habituation (becoming accustomed) occurred within a short time period at Building 3A and, from the consistently high tracking activity and increased licking activity recorded, it is evident that the rodents at the actual field sites became habituated to the ultrasound. Consequently, it does not

invalidate Dr. Shumake's tests that Norway rats were not tested at the pumphouses.

Likewise, the fact that the Sonitron Model Super C was not tested at Building 3A does not render conclusions regarding its effectiveness invalid. Two Sonitron Super C units were tested at the pumphouses with adequate protocol and data collection techniques. As in Building 3A, the ultrasound produced effects which were inconsistent and not statistically significant, according to Drs. Shumake, Howard, and Jacobs. Indeed, a review of data collected at pumphouse 1 and the metal grain storage building yielded minimal or no effects of the Super C units upon rodents. Consequently, the fact that the Super C was not tested at Building 3A is not probative.

Respondent argues that behavioral differences between Norway rats in the two replications adversely affected the test results. On the contrary, this argument supports Dr. Shumake's findings that the effects of ultrasound are inconsistent even within the same species of rodents. Behavioral differences among rodents are inescapable and a measure of the Sonitron's effectiveness should not exclude the rogue rodent behavior in Replication 2. Likewise, the data of Period 2 within each replication is valid in that the testing included a baseline period for rodent activity and the Sonitron unit was placed in the opposite room. As noted previously, Dr. Shumake stated that the "second period of the first replication was designed to insure that extraneous factors such as temperature, noise, odors, and floor texture would not interfere

with assessment of the device". Period 2 of each replication revealed minimal or no effects on the rodents. As a result, Period 2 data further supports the conclusion that the Sonitron units did not have the effectiveness claimed.

In a related argument, respondent asserts that Dr. Shumake erroneously included Period 2 in his statistical analysis at Building 3A because the rodents had already been exposed to ultrasound. Dr. Shumake switched the Sonitron and control rooms in Period 2 of each replication and collected baseline data as he had done for Period 1. He employed the repeated analysis of variance test to the data to compare the data between periods and to compare the effects of ultrasound between replications at Building 3A. He testified that "[t]he repeated measures analysis of variance takes into consideration variance between groups or groupings of data based on the main factors. And it compares that with the overall variation occurring across other kinds of groupings or variation for what happened to all the food locations throughout the experiment and gets an estimate of error variance". [TR 868]. Indeed, he states that the "analysis of variance test is about the most powerful statistical test you can use". [TR 868]. He concluded that the results were not a matter of chance and, therefore, the null hypothesis (i.e. that there is no relationship between ultrasound and food consumption) was not rejected. It is determined that Dr. Shumake's testimony is credible and that he properly included Period 2 in the repeated measures of variance analysis.

Respondent maintains that Sonitron units malfunctioned during the tests at Building 3A and pumphouse 3, that they were not fastened securely, and that the Sonitron units at Building 3A and pumphouse 3 were not installed to achieve maximum effectiveness. However, there is no reliable evidence to support this assertion. Dr. Shumake testified that he heard no sounds from the Model C at pumphouse 3. [TR 1190]. Neither does the record support a finding that the Model C at Building 3A malfunctioned during testing. Respondent offers no oral or documentary evidence to establish that the units malfunctioned during testing other than the assertion that when the Model C was examined after the testing was completed, it "was emitting sound in the sonic range" and was, therefore, malfunctioning. Mr. Cardoza testified that a unit may "go sonic" at any time without reason, and this testimony is unchallenged. [TR 1017]. Consequently, the fact that the Sonitron Model C may have malfunctioned at some point after the tests does not support a finding that a malfunction occurred during testing, particularly since the test report makes no mention of any unit malfunction. Nor can it merely be assumed that persons monitoring the test failed to detect a malfunction, or that, having observed malfunction, they chose to ignore it.

Respondent suggests that there may have been ultrasound leakage into the control room and that Dr. Shumake did not fasten the Model C unit securely to the wall of the test chambers which "may have allowed" it to move during the testing in such a way that sound pressures would have changed. However, respondent points to

no evidence in the record which suggests that the Sonitron unit did move or that there was in fact leakage into the control room during testing. This speculation does not constitute evidence and is insufficient to support a finding that the test results are invalid for these reasons.

Respondent also asserts that Dr. Shumake failed to follow the instructions for the Sonitron units, since the unit in Building 3A was placed approximately 28 feet from the point of entry to the Sonitron room and a Super C unit was placed 4-5 feet from the floor of pumphouse 1. Both units were pointed toward the centers of the rooms in which they were mounted. The record discloses that lower decibel ultrasound is less likely to affect rodent behavior. Indeed, Dr. McCartney testified that mounting a Sonitron unit four to five feet from the floor may be appropriate, notwithstanding the fact that the instructions state that the unit should be six to eight feet from the floor. The fact that the Sonitron unit in pumphouse 1 was placed four to five feet from the floor would seem to bias the test in favor of the respondent, yet the mice exhibited minimal reaction to its presence. With respect to the fact that the units were directed at the food packets on the floor, the instructions which accompany the units state that "[t]he primary signal should be directed toward the area of maximum infestation" and should be "facing downward". Therefore, it is reasonable to find that the "area of maximum infestation" would be the location of the food, rather than an entry point.

Respondent further asserts that sound pressure readings at the

test sites were not adequately monitored. Dr. Shumake's report and testimony establishes that such pressure readings were taken at Building 3A and the pumphouses during a time when the units were activated. He did not observe any malfunction of the units. Respondent offers only a hypothesis that sound pressure readings inside the buildings could have changed. Respondent also argues that Dr. Shumake did not take sound pressure readings in areas surrounding the pumphouses. However, Dr. Shumake testified that he did take such readings during prior testing. Considering the fact that the pumphouses are located in isolated areas and that no outside disturbances were noted in the report, it is reasonable to conclude that ambient sound pressure levels did not significantly change at the pumphouses.

Respondent argues that the "tracking" data is inaccurate because flour, which attracts mice, was used as tracking dust. However, respondent also argues that "licking" activity is a better measure of Sonitron effectiveness in that such activity decreased in the pumphouses. Dr. Shumake testified that "the Sonitron devices were not highly effective in ridding the premises of rodents. We still showed signs of rodent activity in terms of tracks on (floured) tracking tiles, a substantial amount of licking on the tiles." TR. at 70. It is difficult to reconcile these two positions unless it can be said that mice have taste buds in their feet. Notwithstanding this, the weight of the expert testimony and documentary evidence of record does not support a finding that licking activity is more valid than tracking activity as a measure

of the Sonitron's effectiveness, or that the use of flour distorted Dr. Shumake's data with respect to the tracking activity (again, respondent appears confident that the use of flour did not adversely affect licking activity). Respondent urges that it took longer for the mice to lick the flour than to walk on it. However, considering the amount of tracking activity as well as the fact that flour openly covered the tiles, it is not clear that more time was required to lick the tiles than to track them to the extent recorded here.

Respondent also argues that the tracking data is inaccurate in that there was no allowance for a reading in excess of nine per tile. Howard, Drs. Jacobs, McCartney, and Shumake determined that such a data collection technique is adequate. Consistency in data collection at these sites is derived from the fact that baseline measurements contained the same nine sector parameters as did measurements taken during activation of the Sonitron units. The tracking activity data evidences that the Sonitron units were not continuously effective in rodent control, regardless of the number of rodents at the site. Substantial evidence of record supports a finding that use of nine sector tiles did not distort the test results.

Respondent further asserts that the tests at the pumphouses were compromised because no population validation was conducted prior to the studies and the rodents were habituated to the effects of ultrasound because of prior testing at the sites. Ascertaining the actual number of rodents which inhabit a field test site at any

given time is a task undertaken with the highest probability of failure lying ahead. Dr. Shumake measured the level of rodent activity at the sites before, during, and after activation of the Sonitron units. This is sufficient to establish the existence of a rodent population at these sites and the extent of their activity. It was, therefore, unnecessary to perform a head count of rodents at the field sites. With respect to habituation from the testing of prior units at these sites, respondent points to no expert testimony in the record to support its position. However, an assertion that the rodents may have become habituated to ultrasound through prior testing, would, if true, not assist in demonstrating effectiveness of the units.

To state that a device "controls" rodents, complainant's expert Dr. Jacobs testified that such a device must perform at 90% or better in laboratory tests and 70% or better in field tests. In other words, a 90% reduction of rodent activity in Building 3A and a 70% reduction of activity at the pumphouses would have demonstrated control. In addition, to be "effective," the product must repel "at least 80 to 85 percent of the time."

Dr. Jacobs noted that 56.7% of the packets in the Sonitron room at Building 3A were tampered with after the initial three day period, which is "below what [he] calls highly effective." Indeed, he testified that the data from Building 3A indicates that "[u]sed by itself, the unit was not highly effective and, in fact, it was not even very effective." Dr. Jackson maintained that confined rodents "may consume somewhat the same amount of food as they would

under nonultrasonic conditions, but the amount of activity involved to get a the food is greatly increased." Dr. Jackson agreed that the test Building 3A data indicates that any relationship between ultrasound and feeding activity "appears to be inconsistent." He ultimately concluded that the rodents were not deterred by ultrasound in Building 3A. TR .

Respondent argues that, in the initial three day period, the rodents removed food packets closest to the exit ports of the Sonitron room, and that this demonstrates the effect of ultrasound. To the contrary, certain packets closest to the Sonitron unit which were damaged in this initial period of exposure. Moreover, as previously noted, the evidence of record supports a finding that rodents feel most secure near their nests and it is reasonable that they would venture to a food supply nearest to the central area in Replication 1. In addition, data from Replication 2, Period 1 revealed that 25 packets were damaged or removed throughout the Sonitron room during the initial days of testing. As a result, the argument that rodents removed only the packets near the exit ports in Replication 1, Period 1 is inaccurate. To the extent that such behavior was observed, it is consistent with ordinary behavior and does not demonstrate the effectiveness of ultrasound.

Complainant's expert Dr. Howard concluded that the tests "were very conclusive that ultrasonics is not effective." The fact that food packets were disturbed in both rooms at Building 3A, even during the initial three day period with ultrasound, was "very significant that the unit isn't going to be effective rodent

control". Dr. Shumake concluded from his studies that neither the Sonitron Model C or Super C effectively eliminates rodents from an area or controls them. Indeed, he reports that, at Building 3A during Replication 1, Period 1, there was "a 30% decrease in food consumption for (the) first week, but the effect is over essentially after one week." As a consequence, Dr. Shumake further concluded that "neither the Sonitron Model C or the Sonitron Model Super C will enhance bait consumption or trapping success in rodent control programs."

All of the experts agree that rodents may become habituated to ultrasound and, indeed, they did become accustomed to ultrasound at Building 3A. However, respondent asserts that the habituation observed is the consequence of faulty test protocol. Dr. Jackson and Mr. McCartney assert that readings had to be taken within the first 24 hours of the start of the test at Building 3A and the field sites in order to record the initial reaction of the rodents. [TR 1508, 3350, and 3370]. Specifically, Dr. Jackson notes that, with respect to confined rodents, exposure to ultrasound for the first time "initially may well cause the animals to go into a protective environment, into a nest box. But that within a period of hours, within the first 24 hour period, the animals will initiate activity to a food supply."

Drs. Shumake, Jacobs, and Howard assert that readings had to be taken at three day intervals in order to minimize human disturbance. Indeed, the literature which accompanies the Sonitron units states that "the sound of the ultrasound signal forces

reluctant changes in patterns. So allow a minimum of three days from plug-in-time to try to evaluate the effectiveness." Dr. Jacobs states that "rodent control implies more than immediate effect," and he notes that short term effects would be inconsistent with the reasonable expectations of consumers who purchase the Sonitron units.

It will be found that recording data after the first 24 hour period does not compromise the test. It is reasonable that a consumer would want more than a disruption in rodent movements for a 24 hour period. Indeed, it can be fairly stated that a consumer would expect results from the use of a Sonitron unit for as long as it is leased, rented, or owned. Labelling which accompanies the Sonitron units does not state that the Sonitron will merely affect rodent movement patterns for 24 hours; rather, it promises that "Sonitizing (implying the use of Sonitron) is highly effective wherever rodents are to be controlled" and is "proven rodent control". Consequently, the label misleads as to the extent and duration of effects of ultrasound.

Respondent maintains that the rodents were "preconditioned" to find the food packets during the pre-test period so that the effects of ultrasound were mitigated. However, this position goes to the limited effectiveness of ultrasound. In essence, respondent urges that the initial effects of ultrasound would be increased if the rodents did not know where the food was located.

Complainant's expert Dr. Jacobs "cannot conceive of a situation in which rodents are put into an environment or find

themselves in an environment which contains food and that the animals wouldn't learn where the food is and make some adjustments regarding getting it. So in terms of that element of learning regarding food being in a design, I don't see how you can avoid it." The evidence of record establishes that although rodents are cautious animals, they are also inclined to explore. As a result, they will find the food out of necessity or through exploration after losing fear of the sound emitted by the Sonitron within a short time period. Indeed, respondent asserts that ultrasound can be utilized when conventional methods of rodent control fail, thus indicating that rodents already know where the food is in most cases where ultrasound is applied. As a result, the fact that the rodents knew where food packets were located in Building 3A does not invalidate or unreasonably bias the test results.

Respondent also asserts that confinement of the rodents at Building 3A compromises the reliability of the study. Drs. Jackson and McCartney believe that rodents respond to stress by migrating, adapting, or dying. Consequently, they urge that confinement at Building 3A limited the choice of the rodents so that they had to adapt to the ultrasound or die. [TR 1506 and 1528]. However, complainant's expert Dr. Howard testified that confinement of the rodents to Building 3A did not invalidate the study. He "believe(s) that rooms were sufficiently large to give the animals ample opportunity for nervous energy to be expended in traveling around. They could remain out of the ultrasonic room, if they so chose." Considering that the control room contained packets of oat

groats and the central room contained enough lab chow to sustain healthy rats during the test period, it is difficult to find that the rodents had to adapt to ultrasound or die. Even if they had become hungry after eating the food located in the control and central rooms, it is indicative of limited or very brief effectiveness of the Sonitron units that hungry rodents were not controlled, deterred, or repelled.

Moreover, the field test sites, where the rodents did have the choice of "migrating," do not support a finding that the Sonitron units were effective. Dr. Jackson agrees that field mice at the pumphouses could have fed on nearby vegetation, insects, and seed, but states that the ultrasonic units did not rid the pumphouses of mice because the environment outside could have been more "stressful". [TR 2219, 2667]. Dr. Howard notes that "the exploring activity in this reasonably, I assume, open area, still continued even with the units going which shows that (the mice) are not at all frightened by it." Dr. Shumake notes that "[o]n every statistical test performed on (data at pumphouses 1 and 2), there are no significant changes during any of these comparisons, the two baselines or either baseline compared with the three week intervals the devices turned on." Moreover, the data at the metal grain and wood irrigation buildings revealed that the rodents exhibited no effects from the implementation of ultrasound. Consequently, the results at the field sites did not show consistent repellent effects from the use of Sonitron units, or yield statistically significant evidence to support the broad Sonitron label claims.

A rodent population existed at the pumphouses before the tests began. The mice obviously had to eat in order to survive such that they would have to venture beyond the walls of the pumphouses regularly. The fact that the mice still explored areas within the pumphouses, notwithstanding the presence of ultrasound, indicates that the devices did not effectively control, repel, or deter the rodents where it is reasonable to assume the mice could obtain food from nearby sources as they did prior to the tests. A review of data obtained from the field site studies does not demonstrate a consistent reduction of rodent activity by 70% at all of the pumphouses for 80 to 85% of the time. This is so even with the high levels of ultrasound used at the field sites. Consequently, field testing does not support the conclusion that the Sonitron, as an integral part of sonitizing, is "highly effective" wherever rodents are to be controlled or is "proven" rodent control.

Dr. Jackson and Mr. McCartney maintain that ultrasound is less effective against confined or resident rodents than it is for a transient population. Respondent therefore argues that Dr. Shumake's tests yield data relative to resident or confined populations and do not address the effects of ultrasound upon a transient rodent population. Respondent's president maintains that "99% of the use of (Impex) units is in the market for controlling a transient population." However, it must be noted that nearly all of the oral and documentary evidence regarding the efficacy of ultrasound offered by the respondent does not address transient populations; rather, it involves situations where there is rodent

infestation prior to the installation of ultrasonic units.

Complainant's expert Dr. Howard noted that ultrasound may help in a situation where an ultrasonic device of high intensity is directed at one opening in a building and a rodent which does not know what is inside a building and which is afraid of predators, may not linger "to analyze the situation" in a new environment. However, if pressured, the rodent will not be deterred even by these conditions, according to Dr. Howard. Effectiveness in the limited situation described does not justify the claim that Sonitron is "highly effective wherever rodents are to be controlled" and that it is "proven rodent control".

Respondent asserts that "uncontroverted examples" that the Sonitron units are "highly effective" and "proven rodent control" include the following: (1) Replication 1, Period 1 at Building 3A; (2) the Prince Macaroni Company in Lawrence, Massachusetts; (3) pumphouse 2, where there was a mean reduction of 86.9% in licking activity; and (4) Dr. Shumake's Philippine rat study. However, the record does not support arguments that these examples show Sonitron units to be "highly effective" or "proven rodent control".

The testimony of Mr. Farook Taufiq regarding the use of ultrasound at Prince Company, as well as testimony of Mr. Conner, Mr. Mampe, Mr. Cardoza, and Mr. Culver, and the submission of numerous other consumer reports are credible, in that it is clear these individuals believed the units had been effective together with other controls. However, as previously noted, such oral and documentary evidence is entitled to less weight that is given to

controlled tests, because it is not accompanied by data and analysis of scientific quality. Further, this consumer evidence involved the use of ultrasound together with other established methods of rodent control. Consequently, such evidence does not support a finding that the Sonitron units either alone or in combination with other methods provide "highly effective" or "proven" rodent control, and is not dispositive in determining whether the statements at issue in this matter are false or misleading.

With respect to Dr. Shumake's Philippine rat study, three ultrasonic devices were tested, including the Urie One, the predecessor to the Sonitron Model C. The Urie One emitted 118 decibels at one foot. The three ultrasound units were placed in three of four chambers with 10 cm. x 10 cm. entrances. All four chambers contained food and water. Dr. Shumake concluded that "data for the native rat trial suggest that ultrasound at high intensity can produce a response similar to a food neophobia . . . in Philippine rats, especially when the animals have been living in a highly stable, restricted-sound environment for several days before ultrasound is introduced."

The conclusions from this study are limited to a species of Philippine rats and Dr. Shumake recommended that ultrasound be tested with other species of rodents. Rx. 25. Dr. Jacobs likewise testified that the results of the study are limited to its circumstances, i.e. the use of high intensity ultrasound at close range with Philippine rats, which tend to be more neophobic than

other rodent species. Based upon limitations inherent to the Philippine rat study, it is entitled to less weight than other evidence of record in determining whether the Sonitron is "highly effective" or "proven" in rodent control with domestic species, and is not probative as to whether any of the statements at issue in this matter are false or misleading.

Respondent argues that Replication 1, Period 1 at Building 3A supports a finding that the Sonitron is "highly effective" and "proven" in rodent control. Such a circumscribed selection of evidence from the data at Building 3A is not probative. A complete review of the data indicates that the rodents in Replication 1 quickly became acclimated to the ultrasound and did feed in its presence, even during the initial three day period; moreover, the different set of rodents tested in Replication 2 were only minimally affected by the ultrasound. Therefore, the Sonitron units produced inconsistent and short-term effects on the rodents at Building 3A. As a result, it is determined that Replication 1, Period 1, standing alone, does not support a finding that the Sonitron provides "highly effective" or "proven" rodent control. Neither is it probative as to whether other statements at issue in this matter are false and misleading.

Finally, respondent asserts that the data at pumphouse 2, "where there was a mean reduction of 86.9% in licking activity", supports a finding that Sonitron is "highly effective" and "proven" in rodent control. Again, selecting one piece of evidence within a study to support the broad claim of effectiveness would distort

the overall results of the test. Pumphouse 1 demonstrated only a 19.6% decrease in licking activity and Pumphouse 3 evidenced a 71.4% decrease. Drs. Shumake, Jacobs, and Howard concluded that the effects of ultrasound were not statistically significant in any of the pumphouses and that the effects of ultrasound were inconsistent between pumphouses. Moreover, no effects were noted in the metal grain and wood irrigation buildings. The mice entered areas in the presence of ultrasound throughout the test period as the tracking activity was consistently high at all of the pumphouses. As a result, the mean reduction of 86.9% of licking activity at pumphouse 2, standing alone, can not support a finding that the Sonitron is "highly effective" or that it is "proven rodent control" for all of the circumstances and applications to which the product labeling refers without qualification. This evidence is overcome by other evidence in the record, including other parts of the test, which suggest an initial but temporary response, not the "proven rodent control" promised by respondent's labeling.

Having considered all of the foregoing evidence, it is determined that the Sonitron units are not "highly effective" in rodent control and are not "proven rodent control" in the wide variety of circumstances that respondent's unqualified labeling promises. The record amply demonstrates that ultrasound may produce a temporary reaction in some rodents, but no reaction in others. The reaction may take the form of increased movement activity and nervousness. However, rodents become accustomed to

the ultrasound within a short time and, in such cases, any effects which ultrasound produces are severely curtailed. Moreover, rodents which have been previously exposed to ultrasound will exhibit a minimal reaction to it during subsequent exposure. Based upon the foregoing, it will be found that the Sonitron units are not highly effective and proven rodent control, in a wide variety of circumstances, as labeled.

Literature accompanying the ultrasound units also states the following:

While Sonitron will help keep new rodents out of the area and drive old ones out, there are a few cases where old resident rats would--out of force of habit--try to reach the food they know is there, if they have nowhere else to go. It has been observed that food consumption of such rats goes down significantly in the presence of ultrasound.

Respondent offered no scientific studies to establish that the ultrasound will drive old rodents away and "will help keep new rodents out of the area". Rather, respondent asserts that evidence which demonstrates that the Sonitron will drive out old rodents and keep new rodents away from an area includes the following: (1) Replication 1, Period 1 at Building 3A; (2) a man reduction of 86.9% in licking activity at Pumphouse 2; and (3) testimony of Messrs. Taufiq, Culver, Cardoza, and Mampe as well as a number of consumer reports. It has been previously determined that this evidence, standing alone, does not support a finding that ultrasound will drive away old rodents and keep new rodents out of an area when weighed against the studies of scientific quality

conducted by Dr. Shumake, reviewed in their entirety.

Respondent states that the 1949 Calhoun study proposes that "once you establish a behavioral response to the dominant rat, you can remove that rat and have the feeding patterns maintained at least for a period of time." According to Dr. Jackson, a general principle may be extrapolated from the foregoing that rodents would not automatically return to an area if a stimulus, which has been sufficiently aversive, is removed. Respondent submits the following:

The lack of rebound in pumphouse testing, where the rodents failed to return after the Sonitron units had been turned on a second time, could very well be caused as a result of the behavior in Calhoun's study, where the rodents failed to return even though the aversive stimulus is removed.

The foregoing statement is speculative and is not supported by documentary evidence or expert testimony in the record. On the contrary, Dr. Jacobs noted that there was a decline of activity at pumphouse 2 before the test, which indicates the influence of some other factor. Moreover, there is no consistent or statistically significant decline in rodent activity at any of the pumphouses. In sum, this principle is insufficient to support a finding that Sonitron drives out old rodents and keeps new rodents out of an area.

Dr. Shumake's studies, on the other hand, establish that rodents habituate to the ultrasound within a short period of time and continue to feed in its presence. Drs. Shumake, Jackson, Howard, and Jacobs agree that ultrasound has minimal effects upon

established pathways and populations. Dr. Jacobs further notes that a consumer would be unlikely to find ultrasound to be effective in rodent control where an area is cleared only for a short period of time with subsequent reinfestation. In addition, he observed that rodents which have previously been exposed to ultrasound exhibit minimal reaction to it a second time. Dr. Howard states that even a transient rodent in a new environment will not be deterred by high intensity ultrasound if it is hungry or faces a hostile outdoor environment.

Considering the foregoing evidence, it is determined that the statement that "Sonitron will help keep new rodents out of the area and drive old ones out" is overbroad, even in the context of the its paragraph. The preponderance of the evidence in this case does not support such a statement. To the contrary, it appears that "old rodents" are most likely to acclimate themselves to the presence of ultrasound to the extent that the Sonitron units will not drive them out of an area. Transient rodents which are hungry or which face other stresses will not be deterred by ultrasound. From the labelling of the Sonitron units, a customer would reasonably expect an area to be cleared permanently by the use of the units.

The label which accompanyies the Sonitron units further states that "[m]any users of Sonitron ultrasonic units have successfully cleared the area of rodents without a much more complicated approach than by simply plugging in these units." There is no documentary evidence of scientific quality or expert testimony to

embrace such an assertion. The respondent again argues that the following evidence supports findings that ultrasound alone can clear an area of rodents: (1) Replication 1, Period 1 at Building 3A; (2) a mean reduction of 86.9% of licking activity in pumphouse 2; (3) Dr. Shumake's Philippine rat study; and (4) Mr. Connor's cottage in North Woodstock. For reasons previously stated, this evidence is entitled to less probative value and does not support a finding that Sonitron, used alone, will clear an area of rodents.

The respondent also cites 1969 observations by Greaves and Rowe to support the conclusion that ultrasound alone may clear an area of rodents. Dr. Howard states that, when exposed to ultrasound, Greaves and Rowe "were quite excited because (the rodents) did respond when the units were turned on. But they also found that rodents respond to any disturbance that you give them. Any type of strange behavior or activity." Greaves and Rowe observed the effects of high intensity ultrasound in a small chamber in conjunction with a number of other variables, including lighting, hunger, and thirst. In their report, the authors state that some mice and rats will not be deterred by ultrasound and recommend that further testing be conducted. Given the foregoing limitations, the Greaves and Rowe report is entitled to less probative value than other evidence of record in assessing whether ultrasound, used alone, can clear an area of rodents.

Indeed, a preponderance of the expert testimony in this case does not support a finding that ultrasound can clear an area of rodents. Mampe stated that he had "never seen a situation nor can

(he) conceive of a situation where ultrasound would be the only tool permitted." Drs. Jacobs, Howard, and Shumake conclude that the Sonitron units, used alone, are ineffective in rodent control. Dr. Jackson states that ultrasound "obviously cannot be used in a direct cause/effect demonstration"; rather, "it must be used in conjunction with traditional methods of rodent control." There are no studies of scientific quality which show that ultrasound alone can clear an area of rodents. On the contrary, Dr. Shumake's tests reveal the problem of habituation and inconsistent response to ultrasound within a short period. The preponderance of the expert testimony and documentary evidence in this case does not support a finding that ultrasound, used alone, can clear an area of rodents.

Finally, the label which accompanies the Sonitron units states that "Sonitron ultrasonics have introduced advanced technology for more effective rodent control." As previously discussed, the Sonitron units do not provide for "more effective control" of rodents; however, with respect to the assertion that the Sonitron is "advanced technology", some witnesses for the respondent testified that ultrasound is advanced where compared to the use of non-technological methods of control, including baseball bats, baits, and cats. These analogies are of little assistance. The word "advanced" describes the word technology and any comparisons must, therefore, involve technological methods of control. As defined in Webster's Ninth New Collegiate Dictionary, the term "advanced" means "beyond the elementary or introductory". Webster's Ninth New Collegiate Dictionary 59 (9th ed. 1990). Drs.

Howard and Jacobs assert that experimentation with ultrasound as a means of rodent control goes back 30 years and, therefore, the Sonitron is not "advanced" technology.

On the other hand, Dr. Jackson, Mr. Mampe, and Dr. McCartney consider the principle of Sonitron is advanced compared to other technology for rodent control, which includes electromagnetics. The fact that ultrasound was tested for 30 years goes to the issue of whether it is "new" technology and not whether it is technology which is "advanced". Ultrasound emits sound waves which are generally not discernible to the ears of humans or other animals but can be heard by rodents. As a result, although the labeling of the Sonitron units at issue in this case is otherwise misleading, it is determined that the use of the term "advanced technology" is not misleading standing alone, but, in context, to the extent that it contributes to consumer expectations of the effectiveness of the devices for controlling rodents, it has the capacity to mislead.

In considering the appropriateness of the penalty sought for the two "misbranding" violations at issue in this matter, it is noted that the EPA FIFRA penalty policy provides for consideration of the gravity of the violation, the size of the respondent's business, and the effect of payment of the penalty as proposed on the respondent's ability to continue in business. In connection with the gravity of the violation, numerous factors may be taken into account, including the scale and type of use or anticipated use of the product, and evidence of good faith, or lack thereof, in

the circumstances; and the severity of such potential injury. In addition, the extent to which the applicable provisions of the Act were in fact violated may be considered.

All of the above matters having been considered, including evidence of respondent's financial position, good faith, and cooperation throughout the investigation, and there being no evidence of prior violations of the Act, and, above all, the likelihood that these violations have had little potential for injury beyond that which may occur to over-expectant consumers' pocketbooks, it is determined and will be found, that a penalty of \$500.00 per violation is appropriate.

Findings of Fact and Conclusions of Law

1. Mr. Tej Tanden is the president and owner of Impex Industires. He has the equivalent of a Bachelor of Science and a L.L.B. from Banaras University in India. [TR 1328]. He started working in the field of ultrasonics in 1970, and has conducted seminars for manufacturers, government, officials, consultants, and company executives who had rodent problems. [TR 1351-52]. He is certified as an expert in ultrasonics as it relates to auditory responses. [TR 1362].

2. In the fiscal year ending October 30, 1986, a total of 3,300 units were sold which totalled \$153,034.00 in sales. [TR 2710]. The costs of manufacturing the units, including raw materials, totalled \$144,793.00. [TR 2711]. This total does not include salaries for Tej Tanden or A. J. Tanden. [TR 2711].

3. Labeling/accompanying materials for the Sonitrons state that many users of ultrasonic units have successfully cleared the area of rodents without a much more complicated approach than by simply plugging in these units; and that the units provide highly effective and proven rodent control. The materials also urge consumers to use all conventional means of eliminating rodents also, such as baits, blocking entry holes , and covering food. [CX 1]

4. Mr. Robert Kalayjian picked up Sonitron units which were being held or offered for sale, from respondent in July, 1982. He was not informed by respondent that the units were experimental. Respondent's president signed complainant's exhibit 9, the EPA procurement request form. The form provides that the products collected were being held for sale. EPA would have rejected the units if they had been experimental devices. [TR 3392].

5. Respondent's representatives were cooperative at all times. [TR 535-536]

6. In 1979, after testing of electromagnetic devices, EPA made a decision to test ultrasonic devices. [TR 616]. The impetus for testing the ultrasonic units came from Mr. Stubbs' office. [TR 615]. EPA decided to test many different units to observe their frequency, decibel levels, and parameters. [TR 613-14].

7. The manufacturers whose units were obtained were not told that the agency suspected violations of the Act when the units were picked up because "normally the reason for picking them up was for efficacy testing or electronic testing." [TR 618].

8. The decision to bring an enforcement action was made after Mr. Stubbs and Dr. William Jacobs reviewed the efficacy studies conducted by Dr. Shumake. [TR 627].

9. Mr. Ira Leonard was certified as an expert in sound and acoustics. [TR 11]

10. Dr. Steven A. Shumake conducted laboratory and field testing of the Model C and Super C devices beginning in July, 1982. He is employed by the U.S. Department of Agriculture at the Denver Wildlife Research Center as a Research Psychologist. [TR 282]. He has a Masters and a Ph. D. Degree in Experimental Psychology. [TR 283]. He has published 30 articles in his field. [TR 284]. His responsibilities at the Denver Wildlife Research Center are "to develop new methods for controlling damage by vertebrate pest species and to evaluate or test traditional or commercially made devices or products for controlling these animals." [TR 284]. From the beginning of his efficacy studies, he believed

. . . that the book was still open on the efficacy for these devices." [TR 617]. Respondent was not "targeted" by the agency. [TR 619-620]. He is certified in the field of experimental psychology, as it relates to animals, which includes, sensory perceptions, learning, motivation, and emotion. [TR 364]

11. Dr. Shumake tested the Sonitron Model C in Building 3A from June 21, 1982 to October 7, 1982. Two Sonitron Model Super Cs were tested at field sites from June 14, 1983 to August 16, 1983. Two model Super Cs were also tested at a metal grain building and a wood irrigation building from July 6, 1982 to October 5, 1982. All

three units were subsequently tested at isolated pumphouses. Shumake's report is submitted as Complainant's Exhibit 14. [TR 366]. There was literature inside the Super C cartons received from Gerald Stubbs, i.e. Complainant's Exhibit 1. [TR 366-67].

12. Prior to the tests he met with Keith Lavoie to establish testing protocol. [TR 678]. He also consulted Drs. Bridenstein and Otis to establish testing protocols and methods of statistical evaluation of the data. [TR 679 and 681]. The test protocols were adequate for the test objectives.

13. In Building 3A, there were inconsistent effects of ultrasound within each replication and across replications. [TR 412]. In Replication 1, Period 1, there was "a 30% decrease in food consumption for (the) first week, but the effect is over essentially after one week." [TR 415-16]. For the room "instrumented with the Sonitron device," there was an increase in photocell break activity and an increase in food consumption over the two week period and this period. [TR 432].

14. Dr. Shumake's tests demonstrate that the Sonitron Model C and Super C do not effectively eliminate rodents or control them. [Tr 439, 500, and 520]. Using the Chi-square and Wilcoxon analysis for the field site data, he found that "[t]he decrease in activity shown during the ultrasound period, varied in the neighborhood of about 20 to 30%" [TR 499]. He further found that "[o]n every statistical test performed (on data from pumphouses 1 and 2), there were no significant changes during any of these comparisons, the two baselines or either baseline compared with the three week

interval the devices were turned on. [TR 507].

15. With respect to protocol at Building 3A, a 15% temperature change did not bias the test results. "Temperature range (is) . . . not the main controlling factors for rodent behavior." [TR 778-798]. Rodents live in sub-freezing temperatures to temperatures in excess of 90 degrees. [TR 798]. The garage door on the west side of the building "had no influence on the rats' movements." [TR 750]..

16. Statistical tests "aim towards trying to derive some measure of probability of obtaining a difference in a set of data looking at the variability within the readings to see whether this was occurring by chance, uncontrolled factors, or whether it was associated with an independent variable, in this case, ultrasound versus no ultrasound." [TR 851].

17. The Wilcoxon rank sum statistic was used to compare photocell breaks in the east and west rooms of Building 3A during replications. [TR 825-26].

18. The Chi-square test was not used for food consumption "[b]ecause that test is not as powerful as the repeated measures test, in terms of rejecting the null hypothesis." [TRt 866-87].

19. The main effects of confinement on rodents is that they form a social hierarchy: "Different ones will feed at different times. Different locations will be explored by the rats." [TR 972].

20. The extent of rodent activity can be determined from photocell breaks and rodent count. [TR 988-89].

21. The death of two rats out of 24 during the test period is not unusual and does not invalidate the test. [TR 1303-1305].

22. Neither the Sonitron Model C nor the Sonitron Model Super C will enhance bait consumption or trapping success in rodent control programs. [TR 534].

23. The tests conducted by Dr. Shumake at the pumphouses did not show effectiveness of the ultrasonic unit in field conditions. [TR 900]. Exploring activity in this reasonably open area, still continued even with the units going which shows that the mice) are not at all frightened by it. [TR 909].

24. The inability on the part of the rodents to leave the building did not invalidate the testing at Building 3A. The rooms were sufficiently large to give the animals ample opportunity for nervous energy to be expended in travelling around. They could remain out of the ultrasonic room, if they so chose." [TR 1265].

25. The fact that data was not collected within the first 24 hours of the test, to minimize disturbance by humans, and to test long-term effects, did not invalidate the test results or make them less probative of Sonitron effectiveness. [TR 874].

26. "[T]he longer (that the rodents are) exposed to the sound, the less likely they are to turn away." [TR 879]

27. The tests "were very conclusive that ultrasonics is not effective." [TR 891]. The fact that packets were tampered with in both rooms, even in the first three day period, was "very significant that the unit isn't going to be effective in rodent control." [TR 885]

28. The studies are "adequate for evaluating repellency" and "to the extent that the numbers reported are accurate, the interpretations (Dr. Shumake's) drawn from the data are reasonable." [TR 1527].

29. The fact that packets were not glued to the floor in Dr. Shumake's study does not represent a significant flaw in design. [TR 3534 and 3537]

30. A rodent would tend to remove food in most cases if it had the choice of consuming food either in an open area or in a safe, dark place. [TR 3531].

31. After the first three days in Building 3A, 56.7% of the packets were tampered with in the "Sonitron room". This is below a highly effective level. [TR 310]. To the extent that a repellent effect was observed on July 1st, that effect had waned considerably and all but disappeared by July 5th. [TR 335]. Indeed, 100% of the packets in the control room, and 87% of the packets in the Sonitron room, were removed or torn which is "a very small effect, not an effect that would satisfy someone owning the building and getting that result." [TR 336].

32. Upon review of Dr. Shumake's studies at Building 3A and the pumphouses, Mr. Stubbs concluded that "there seems to be some initial repellency that diminishes rapidly and the products don't repel or eliminate rodents on their own." [TR 485].

33. Prior to Dr. Shumake's studies, EPA was not "looking for any outcome or conclusions," and "thought it would be a benefit to the environment, and had not formed conclusions as to the efficacy of

the units." [TR 563].

34. The effect of ultrasound upon rodents is not "significant" unless it is "both statistically significant and large in magnitude." [TR 84].

35. To achieve "control", the device must perform 90% or better in laboratory tests and 70% or better in field tests. [TR 156]. In other words, there must be a 70% reduction in rodent activity at the field site as measured in the study. [TR 157].

36. To be effective, a product would have to produce at least a 70% percent repellency effect, at least 80 to 85 percent of the time. [TR 295].

37. Rodent "control" implies more than an immediate but short-term effect. [TR 249].

38. Dr. William Jacobs is a biologist in the Insecticide/Rodenticide Branch, Technical Support Section, Registration Division, of the Office of Pesticide Programs at the agency. [TR 1316]. He is qualified as an expert in test protocols, rodent behavior, and labeling. [TR 1515-16]. He reviews labels for "vertebrate pesticides" at the agency. [TR 1627].

39. Jacobs first spoke with the agency's enforcement branch regarding ultrasound efficacy when Mr. Gerald Stubbs sent the Adam Baum egg farm study and some literature to him to review on July 5, 1979. [TR 12]. Jacobs returned the materials on July 18, 1979.

40. On April 20, 1981, Mr. Stubbs sent Dr. Jacobs the protocol for Dr. Shumake's studies at Building 3A and the field sites to review.

[TR 7, 9]. Dr. Jacobs approved of the protocol to be used.

41. On November 8, 1983, Dr. Jacobs received the results of Dr. Shumake's tests from Mr. Stubbs. [TR 49]. Dr. Jacobs then sent his review of the results to Stubbs on November 21, 1983. [TR 50 and 54].

42. Complainant's expert witness Dr. Howard has conducted numerous tests on rodents and has published articles in Pest Control, Pest Control Tech, and The Rotarian. [TR 741, 744 and 745]. Dr. Howard is certified as an expert in rodent control. [TR 720, 730 and 1017].

43. The protocol and results of Philippine rat study were acceptable, rodent control was not addressed. Rather, "[i]t was a test of rodent behavior and response to units." [TR 750].

44. With respect to the 1969 Greaves and Rowe study, rodents, when exposed to ultrasound, "were quite excited because (they) did respond when the units were turned on. But [the authors] also found that rodents respond to any disturbance that you give them. Any type of strange behavior or activity." [TR 752].

45. Dr. Howard notes that, with respect to Jackson's egg farm study, he spoke with us peers and "we have reached mutual agreement that we did not think it was a scientific study with adequate controls." [TR 754].

46. Dr. Howard conducted a test of the effects of ultrasound in 1960 using ten wild rats. There were three chambers: the bottom chamber had food and water; the middle chamber was for nesting; and the top chamber had only an ultrasonic unit in it. [TR 789-99].

Within the 24-hour period the rats "entered the sound barrier and often carried food into the sound barrier to eat it even though the sound was there." [TR 799]. Howard concludes that "rodents grow accustomed to sound--either quickly or in a matter of days." [TR 810].

47. The Adam Baum egg farm study was "not good science." [TR 1580].

48. The General Nutrition Stores study was "not a well designed, well monitored study." [TR 1582]. There were problems with the maintenance of the tracking patches as well as a problem with the units being truned on and off throughout the testing. In addition, the results at the Temple Street store showed significant activity in the basement throughout the study. At the Boylston Street store, rodent activity persisted for over a month and "further activity ceased" after Talon bait was used. [TR 1582-83].

49. The super Value Store was not a study, "but an account with recommendations." The ultrasound levels were too low to be effective. [TR 1385].

50. At the Pritts grain mill, there was "no independent measure of activity" because other methods of control were employed.. [TR 1588-95].

51. Mr. Farook Tanfiq is Vice President of Quality Assurance for Prince Macaroni Company. He is responsible for rodent control at all five food manufacturing plant nationwide. [TR 1906 and 1908].

52. Prince Company manufactures "about 150 million pounds of dry goods, spaghetti, macaroni and noodles" each year as well as "over a million gallons of spaghetti sauce." [TR 1907-1908]. In addition, Prince Company "purchases and packages two million pounds of cheese." [TR 1908]. Prince Company purchased a plant in Lawrence, Massachusetts in 1973 and, according to Taufiq, "it was very heavily infested with rodents." [TR 1909]. Using traditional methods of trapping, "about 30 to 40 mice" were caught each day. [TR 1909]. All entrances to the building could not be closed because the shipping docks had "to be open in order for the trucks to be loaded." [TR 1910].

53. Approximately 30 Sonitron Model C units were mounted "all around the building at every possible entry." Mr. Taufiq believes that [w]ithin two months the population of the rodents inside the building was "down to zero." [TR 1910, 1916]. Mr. Taufiq stated that he "trapped inside whatever was there and we kept rodents from coming in from the outside." [TR 1910].

54. Mr. Taufiq reported that he had no problems with rodents after installing the units. [TR 1914]. Taufiq testified that approximately 20 people are on the loading docks during the day and there is a lot of noise. [TR 1923]. The doors to the facility were closed at night. [TR 1922]. He testified that, because a substantial amount of money was spent on the units, he made sure that the employees ran the traps, baits, and poisons, and kept the building clean on the inside. [TR 1927-28]. Ten to fifteen rodent burrows near the building were filled with poison.

[TR 1940].

55. The traps at Lowell plant caught between 25 to 40 mice per day, seven days a week, for four months. [TR 1958-59]. According to Mr. Taufiq, this program eliminated between 3,000 and 5,000 mice, [TR 1959] and even more mice were killed by baits and poisons outside the building. [TR 1960]. The units were installed at the conclusion of a four month period and, Mr. Taufiq testified, two months later the rodent problem disappeared. [TR 1961, 1968].

56. Mr. Robert Conner installed ultrasound units at a cottage he bought at North Woodstock, New Hampshire in 1979. [TR 1547]. No one had lived in the cottage for two years and it was infested with mice. [TR 1547]. He tried to rid the cottage of mice by using D-con, mothballs, and poison but he reported, he was unsuccessful. [TR 1497-98]. He plugged the holes in the cottage with steel wool and set about four traps. [TR 1557]. He bought the "Impex Ridder" in 1981 and was bothered by the sound it made, so he used traps while he was at the cottage and used the Impex Ridder when he was away. [TR 1548 and 1557-58]. He still puts "poison underneath the house and it's still being eaten, but there's nothing in the house." [TR 1580]. He never left food out in the open. [TR 1562].

57. Mr. George Cardoza is Vice President and General Manager of Griggs and Brown Company which distributes Sonitron products, to the extent of between \$15,000 - \$17,000 a year. [TR 2357, 2362, and 2421]. Cardoza is the Governor's appointee to the Rhode Island State Pesticide Advisory Board as well as to the Massachusetts

State Pesticide Advisory Board. [TR 2358]. He is certified as an expert in rodent control programs for New England species. [TR 2392]. He does not know if a Sonitron unit alone could rid an area of rodents. [TR 2412-13].

58. Where he utilizes untrasonics, he has "always" used other control techniques such as baits, closing holes, sanitizing, glueboards, and, at times, traps. [TR 2429-34]. He testified that ultrasonics is used to move rodents from one place to another, but that he has not yet observed that use of ultrasound will eliminate the rodents. [TR 2422].

59. Dr. Charles Mampe has a Ph.D. in entomology (the branch of zoology deals with insects) from North Carolina State University. [TR 2054]. He attended a five day course at rodent control school conducted by the U. S. Public Health Service. [TR 2057]. He has presented seminars in rodent control and has a monthly column in the magazine Pest Control. [TR 2058].

60. In his column in Pest Control Dr. Mampe has never recommended use of the Sonitron alone. [TR 2116]. Indeed, he stated that he has "never seen a situation nor can I conceive of a situation where ultrasound would be the only tool permitted." [TR 2122].

61. Mr. Edward Culver is the President of Monadnock Company, a manufacturer of ultrasonic devices. [TR 1737]. He has 40 years of experience in marketing. [TR 1775].

62. Prior to forming Manadnock Company, Mr. Culver owned and operated a marketing consulting company, Culver International. In 1976, Culver International took over respondent's marketing. [TR

1740]. Mr. Culver was the marketing manager of Impex from 1976-79. [TR 1845]. Mr. Culver helped to draft the brochure which accompanied the Model C. [TR 1849]; Respondent's Exhibit (RX) C1. 63. Mr. Culver had respondent's letterhead and worked out of his own home as an outside consultant. [TR 1740-41]. His "efforts were to establish sales directly to the consumer and also through distributors to pest control operator market." [TR 1744]. 64. Mr. Culver conducted a survey of Tanden's customers based upon warranty of merchantability cards. He received responses from 50% of the consumers. 70% of those returned were positive. [TR 1743-45, 1748; RX D-1. Instructions included with the units required the use of conventional rodent control methods. [TR 1857]. 65. Culver thought that the egg farm would be a "great study in ultrasonics," and contacted Jackson to undertake the study which would be funded by Tanden. [TR 1759]. The rodents were never completely eliminated but he stated that "Adam was pretty happy with the reduced level of damage . . ." [TR 1760]. 66. Mr. Culver introduced respondent's president, Mr. Tanden, to Dr. William Jackson several years ago. Mr. Tanden then hired Dr. Jackson to conduct the Adam Baum study. [TR 2833]. Dr. Jackson and Mr. Tanden subsequently became business partners of Rodent Management, Incorporated. They held seminars in rodent control. [TR 2833-34]. They continue to have an intermittent business relationship. [TR 2835-36]. 67. The Sonitron unit would not be tested along with conventional rodent control methods because "there would be no way, under such

regime, of determining the proportion, if any, of the treatment effects which were due to the device or [which were due] to any of the other variables" [TR 20]. There would be "no way of determining whether ultrasonics were having a repellent effect." [TR 1267].

68. Conventional methods do not fail if they are properly used. [TR 861].

69. Accordingly, it was reasonable and proper to test for the effects of Sonitron alone.

70. It was reasonable and proper to test for the effects of ultrasound over a long period, and to make observations over a longer period than 24 hours. Accordingly, the results of Dr. Shumake's tests are not invalid or nonprobative, or entitled to less weight because the first observations were made after three days (rather than after 24 hours) and thereafter at three day intervals for the duration of the test.

71. Ultrasound may help only if the following conditions are met: (1) ultrasonic device of high intensity directed at one opening in a building; (2) the rodent does not know what is inside the building; (3) the rodent is afraid of predators and "is not going to stay there long to analyze the situation"; and (4) a new environment. [TR 864]. However, "if (the rodent is) pressured, then (he/she will) go through most of these conditions." [TR 868].

72. This action was lawfully commenced pursuant to 7 U.S.C. 136(1)(a), without certifying the facts to the Attorney General. Respondent engaged in the promotion, sale, and distribution of the

products Sonitron Model C and Sonitron Model Super C, which are "devices" within the meaning of 7 U.S.C. §136(h), FIFRA §2(h), 40 CFR §162.15. Respondent is a "person" within the meaning of 7 U.S.C. 136(s), FIFRA §2(s), and is, therefore, subject to the provisions of the Act. Respondent is a "producer" within the definition of 7 U.S.C. 136(w), FIFRA §2(w) which includes a persons who "prepare" or "process" a device.

73. Respondent held for sale the Sonitron Model C and Sonitron Model Super C at the time the units were picked up by Mr. Robert Kalajian.

74. At the time the units were received EPA did not suspect a violation of the Act.

75. The labeling which accompanies the above-named devices states that they are "advanced technology" which provide "effective" and "proven" rodent control and that they will keep new rodents out of an area while driving away old rodents. In addition, it is claimed that "[m]any users of Sonitron ultrasonic units have successfully cleared the area of rodents without a much more complicated approach than by simply plugging in these units". These statements taken together, imply long term effectiveness at a level of 70-100% to purchasers; the labeling further implies that Sonitron units, alone or as an essential part of a total control system, will provide long term control at such levels. [TR 422-424, 295, 156-157, 84, 485].

76. However, the devices are neither "effective" nor "proven" in rodent control in the unlimited manner promised by the labeling.

The Sonitron Model C or Super C units are not an essential part of an integrated pest control program because rodents are not uniformly, consistently, or permanently deterred by ultrasound, and because conventional methods are fully effective if used properly. In those cases where ultrasound has produced minimal effects, such effects are inconsistent and short term due to habituation. No evidence of scientific quality in this record suggests or supports a finding that the Sonitron units, used alone, are able to clear an area of rodents for a substantial period of time.

77. Consumer evidence is entitled to less weight than is given to evidence in the form of scientific tests and disinterested expert opinion. The consumer evidence in this record is not accompanied by protocols, trained observers' notes or other indicia of exact, reliable, and systematic testing.

78. Opinions of experts having a financial interest in the success of products under examination are entitled to less weight than those of disinterested experts. Substantial evidence of record supports the finding that the ultrasound units here do not offer effective or proven rodent control. Accordingly, the Sonitron Model C and Sonitron Model Super C were "misbranded", as the term is defined at 7 U.S.C. §136(q)(1), as made applicable by 40 C.F.R. §162.15, owing to the unsupported breadth of claims made.

79. The above named devices are "advanced technology" in the sense that they rely upon means other than direct killing, traps, poison or other age-old restraints to achieve the limited effects they can produce. To the extent that the term "advanced technology"

suggests control and effectiveness promised, however, the term is misleading. The devices are neither "effective" nor "proven" in rodent control in the unlimited manner promised by the labeling.

80. The Sonitron Model C or Super C units are not an essential part of an integrated pest control program, since the record establishes that rodents are not deterred by ultrasound and that, in those cases where the ultrasound has produced minimal effects, such effects are inconsistent and short term. There is no evidence of scientific quality which suggests that the Sonitron units, used alone, are able to clear an area of rodents for a substantial period of time. Substantial evidence of record supports the finding that the ultrasound units here do not offer effective or proven rodent control. Accordingly, the Sonitron Model C and Sonitron Model Super C are "misbranded", as the term is defined at 7 U.S.C. §136(q)(1)(A), as made applicable by 40 C.F.R. 162.15.


81. Therefore, respondent, which manufactured and sold the above-named devices, is in violation of 7 U.S.C. §136(j)(a)(1)(f), §12(a)(1)(F) of the Act and may be assessed a civil penalty in accordance with 7 U.S.C. §136(l)(a)(1), §14(a)(1) of the Act.

82. A civil penalty of \$500 per violation, or \$1,000 total, is reasonable, all relevant circumstances having been taken into account.

FINAL ORDER

Accordingly, it is ORDERED, pursuant to section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. §136(1)(a)(1), and upon consideration of the entire record herein, after evaluating the gravity of the violations and the appropriateness of the penalty proposed, that the respondent Impex Industries, pay, within sixty (60) days of service upon it of the final order, the amount of \$1,000.00 as a civil penalty for violations of the said Act by forwarding to the Regional Hearing Clerk a cashier's check or a certified check for the said amount payable to:

U. S. Environmental Protection Agency
Region I
P. O. Box 360197M
Pittsburgh, PA 15251



J. F. Greene
Administrative Law Judge

Dated: June 27, 1991
Washington, D.C.

In the Matter of
Impex Industries, Inc.
Docket No. FIFRA I-84-1048

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Letter Transmitting Judge Greene's Initial Decision was sent to the following persons in the following manner:

U.S. EPA Pouch Mail:

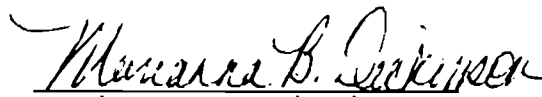
Michael J. Walker, Esq.
Assistant Enforcement Counsel
U.S. Environmental Protection Agency
401 M Street, S.W.
Mail Code LE-134P
Washington, DC 20460

Certified Mail
Return Receipt Requested:

Edward A. Sokoloff, Esq.
20 Nason Street
Maynard, MA 01754

I further certify that the original copy of the Decision, together with the Record in this matter, were filed with the Hearing Clerk, Headquarters, by U.S. EPA Pouch Mail and that a copy of the Decision, Cover Letter and Certificate of Service were filed with the Regional Hearing Clerk, U.S. EPA, Region I.

7-3-91
Date


Marianna B. Dickinson
Regional Hearing Clerk