UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 22, 1989

A-110

OFFICE OF
THE ADMINISTRATOR

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

(See List of Addressees Attached)

Subject: In re Protexall Products, Inc., et al.;
FIFRA Docket Nos. 625, et al.

To the Parties:

Transmitted herewith are copies of the "Initial Decision", "Certification of Transcript" and "Order Denying Respondent's Motion To Admit Into Evidence Certain Exhibits" all dated and filed May 22, 1989 in the above-entitled proceedings by Chief Administrative Law Judge Gerald Harwood.

Sincerely,

Bessie L. Hammiel,
Hearing Clerk

Enclosures (3)

cc: Ronald L. McCallum, Chief Judicial Officer

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of	)	
	)	
Protexall Products, Inc., et al.,	)	FIFRA Docket Nos. 625, et al.
	)	
Petitioners	)	

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INITIAL DECISION

PRELIMINARY STATEMENT

This is a proceeding brought under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), § 6(b), 7 U.S.C. 136d(b). It was instituted by the Administrator's notice of his intent to cancel registrations for inorganic arsenical pesticide products registered for non wood-preservative use, published on June 30, 1988 (hereafter referred to as the "Notice"). 1/ The Notice stated that it announced the Administrator's final determination to cancel registrations and deny applications for registration for all nonwood use pesticide products that contain the inorganic arsenicals lead arsenate, calcium arsenate, sodium arsenate and sodium arsenite except for certain agricultural uses. 2/ The Notice further stated that it also announced the Administrator's determination to cancel all registrations and deny applications for registration of all non-wood-preservative use pesticide products containing arsenic trioxide except for the solid formulations to control ants (packaged in a sealed metal container) and moles, gophers, and pocket gophers. 3/

Five registrants of inorganic arsenical pesticides filed objections and requested a hearing. Four were registrants of insecticides containing

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1/ 53 Fed. Reg. 24787. The notice is included in the record in this case as EPA Exhibit 157.

2/ The exceptions were considered to be the "major" non-wood uses of inorganic arsenicals and consisted of the turf herbicidal use of the flowable formulation of calcium arsenate, the grapefruit growth regulator use of lead arsenate, and the grape fungicidal use of sodium arsenite. These three uses and the desiccant uses of arsenic acid on okra (grown for seed) and cotton were stated to be still under "Special Review", i.e., being evaluated to determine whether they should be cancelled (see 40 C.F.R. § 152.146). Notice, at 24787, 24788.

3/ Id.

sodium arsenate, in each case a household product sold to kill ants. 4/ The fifth company was the registrant of an insecticide containing arsenic trioxide also sold to kill ants. 5/ This registrant, subsequently withdrew its objections. 6/ Consequently, the hearing on the notice of cancellation has been with respect to the continued registration of ant killers containing sodium arsenate. The presentation of the evidence in support of continued registration has been left to Senoret Chemical Company registrant of "Terro Ant Killer," (hereafter referred to as "Senoret"). The other three registrants of sodium arsenate ant killer products elected to be "inactive parties", that is, not to participate in the presentation of evidence, but to have the right to file post-hearing briefs and all appeal rights of a party. 7/

The presentation of testimony began in Washington, D.C. on January 23, 1989, and continued through February 23, 1989. Following the submission of briefs and reply briefs, the hearing was closed on April 27, 1989. In addition to the initial and reply briefs filed by the EPA and Senoret, Jones Products, Inc. also filed a brief. EPA's motion to strike or for leave to file a response to Petitioner Senoret's reply, filed after the record was closed, is denied.

4/ The four sodium arsenate ant killer product registrants were Protexall Products, Inc., registrant of "Ant Kill"; Jones Products, Inc., registrant of "Jones Ant Killer; Senoret Chemical Company, registrant of "Terro Ant Killer" and FATSCO, registrant of "FATSCO Ant Poison".

5/ The product was "ANT-JEX REDWOOD ANT STAKES" sold by General Pest Service Co.

6/ See letter to Bessie L. Hammiel, Hearing Clerk from Schmeltzer, Aptaker & Sheppard dated November 23, 1988.

7/ See Report of First Prehearing Conference held on September 28, 1988, at 2.

On consideration of the entire record, the following initial decision is hereby rendered. Proposed findings of fact inconsistent with this decision are rejected. It is also to be noted that citations to support the decision are not intended to include all record support for the point cited. 8/

I. The Notice of Intent to Cancel

The Notice announced that with certain exceptions all pesticide products containing the inorganic arsenicals lead arsenate, calcium arsenate, sodium arsenate, arsenic trioxide and sodium arsenite which are used as other than as a wood preservative were being cancelled. 9/ The cancelled uses were described as the "minor" non-wood-preservative uses. 10/

The EPA noted that the adverse effects of concern generally associated with inorganic arsenicals are oncogenicity, mutagenicity and

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8/ References to the transcript of the record will be cited as "Tr." and the page number, e.g., Tr. 84 refers to page 84 of the transcript. References to the EPA's exhibits will be cited as "EPA Ex." with the exhibit nunber. If the exhibit has several pages, the page number will be in parenthesis, e.g., EPA Ex. 1 (p. 12) refers to page 12 of EPA Exhibit 1. Petitioner Senoret's exhibits will be cited as "Senoret Ex." with the exhibit number (and page in parenthesis where appropriate). EPA cross-examination exhibits will be cited as "EPA Cross Ex." and Petitioner Senoret's cross-examination exhibit will be cited as "Senoret Cross. Ex."

9/ Lead arsenate, calcium arsenate and sodium arsenate are pentavalent inorganic arsenicals. Sodium arsenite and arsenic trioxide are trivalent inoganic arsenicals. Notice, 53 Fed. Reg. at 24789; see also, EPA Exhibit 27.

10/ See Notice, 53 Fed. Reg. at 24788. The excepted uses still under special review were considered to be the "major" non-wood uses. Id.

teratogenicity. 11/ The adverse effect, however, that specifically underlay the cancellation of the sodium arsenate ant killers involved in this proceeding was the acute toxicity of sodium arsenate. Although much less acutely toxic than trivalent arsenicals, pentavalent arsenicals are classified by the EPA in the same acute toxicity Category I, the most toxic category. 12/ The EPA, accordingly, considered the acute toxicity of both pentavalent and trivalent arsenicals together as a group.

The EPA pointed out that information reported to its Pesticide Information Monitoring System ("PIMS") indicated that a significant number of poisoning incidents have occurred as a result of the accidental ingestion of arsenical rodenticides containing arsenic trioxide and insect baits containing sodium arsenite, sodium arsenate and lead arsenate. The majority of incidents involved children. 13/ Of the inorganic arsenical pesticides involved in these poisonings, the only ones of current concern were sodium arsenate ant baits and arsenic trioxide

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11/ Notice, 53 Fed. Reg. at 24789. The oncogenic risks were estimated on the basis of inhalation exposure to applicators and mixer/loaders. In the case of sodium arsenate ant killers the EPA found that this risk was either non-existent, because there is no mixing or loading as the product is sold ready for use, or else the risk was negligible. The EPA was also unable to quantify the mutagenic or teratogenic risks because of the inadequacy of the available information on these risks. Notice, 53 Fed. Reg. at 24790.

12/ Notice, 53 Fed. Reg. 24789. See 40 C.F.R. § 156.10(h)(1) for toxic categories.

13/ Notice, 53 Fed. Reg. at 24789.

insecticides sold in formulations other than the solid formulation. 14/ For purposes of this proceeding it is necessary to discuss only the EPA's findings with respect to the acute toxicity of sodium arsenate ant baits. 15/

With respect to the acute toxicity of sodium arsenate ant baits, the EPA rejected the comment by Senoret Chemical Company, petitioner in this proceeding, that its product ("Terro Ant Killer") was only slightly toxic and the product cannot be judged by the high number of pesticide poisonings reported in connection with it. In its response the EPA referred to certain documentation which it said led it to conclude that exposure to ant baits containing sodium arsenate continues to be a leading cause of child poisonings. 16/

First, the EPA referred to a study by the Colorado Pesticide Hazard Assessment Project completed in 1985, of hospitalizations during 1971 through 1976 resulting from pesticide poisonings. The study estimated that sodium arsenate ant killers were responsible for 37 hospitalizations

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14/ Registration for insecticide baits containing sodium arsenite and lead arsenate have been voluntarily cancelled. Notice, 53 Fed. Reg. at 24789. The solid formulations of arsenic trioxide were found not to present a risk of acute toxicity. Notice, 53 Fed. Reg. at 24789-90; 24793.

15/ Only one producer of an arsenic trioxide insecticide sold in other than a solid formulation filed objections to the Notice and requested a hearing. This producer subsequently withdrew its request for a hearing. See supra, p. 3. Its registration consequently became cancelled by operation of law as did the registrations of all other registrants affected by the Notice who did not request a hearing. Notice, 53 Fed. Reg. at 24795.

16/ Notice, 53 Fed. Reg. at 24792.

nationwide per year. Terro Ant Killer alone was estimated to be responsible for 29 hospitalizations nationwide per year. The EPA pointed out that hospitalized cases receive treatments that are quite stressful for the child and parents, such as injections, pumping of the stomach and administration of syrup of ipecac to induce vomiting, which treatment puts an already traumatized child at further risk of injury or death.

Second, the EPA referred to incident reports of arsenic exposure to ant baits from three Poison Control Centers which also disclosed the risk of acute toxicity from sodium arsenate ant killer. These three centers were: Blodgett Regional Poison Control Center in Grand Rapids, Michigan; the Children's Hospital Poison Control Center of Detroit, Michigan; and the Texas Tech University Health Sciences Center of Lubbock, Texas. The Blodgett Center reported that in 1985, 56 cases of acute arsenic exposure were referred to it. The Children's Hospital Poison Control Center reported that in 1986, 37 cases of human exposure to arsenical pesticides were referred to it. Most of the cases reported to these centers involved exposure of children age 7 and under to Terro Ant Killer through oral contact with or ingestion of the bait station, who were treated for arsenic poisoning. Another sodium arsenate product involved in the exposures of children reported to the Children's Hospital Poison Control Center and treated for arsenic poisoning was Jones Ant Killer. In addition to exposure to the bait station, some exposures directly from the container itself were also reported. 17/

17/ Notice, 53 Fed. Reg. at 24792.

The third center, Texas Tech University Health Center reported that in 1986, 20 calls identifying Terro Ant Killer as the causative agent in a pesticide exposure were received by the National Pesticides Telecommunication Network located at the Center. 18/ The Center also cited a study analyzing 20 cases of arsenic poisoning reported to the Minnesota State Board of Health from 1976 through 1979. Six of the cases were the result of accidental exposure to Terro and five were children. 19/

The EPA concluded that a clear pattern of poisonings emerges from the above data and that the more recent data indicates that a substantial number of poisoning incidents may be occurring nationwide. 20/

Analyzing the benefits of continued use of sodium arsenate ant killers, the EPA rejected the claims of Senoret Chemical Co. that alternative ant killers were not as effective as its product in controlling ants. The EPA said that there are alternative pesticides that are effective in controlling sweet-eating ants in domestic dwellings (the market served by Senoret) that do not pose the risks associated with sodium arsenate liquid ant baits. Alternative active ingredients identified by the EPA included chlorpyrifos, diazinon, propoxur and boric acid. Alternative formulations and methods of dispensation identified by the EPA included

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18/ Notice, 53 Fed. Reg. at 24792.

19/ Notice, 53 Fed. Reg. at 24793.

20/ Senoret Chemical Company also questioned the significance of the EPA's estimate that a spillage of 6 millilitres of sodium aresenate ant killer would result in a dermal exposure of 78 milligrams of arsenic per incident. The EPA responded that it did not rely on dermal exposure in deciding to cancel the insecticidal use of sodium arsenate but on the large number of documented poisoning incidents demonstrating the acute oral toxicity of sodium arsenate insecticide, particularly to children. It added, however, that any additional risk due to dermal exposure would only heigthen the EPA's concern. Notice, 53 Fed. Reg. at 24793.

aerosol sprays and baits contained in packaging which precludes exposure to humans. The EPA said that although they may not be as effective as Senoret's product in controlling sweet-eating ants, the alternatives were considered preferable alternatives because of the negligible acute hazard posed by their use. 21/

The EPA also rejected the claim by Jones Chemical Co., Ltd. that the risk involved in continued use of its liquid sodium arsenate insecticide was negligible and far outweighed by the health and safety benefits to the users. The EPA found that sweet-eating ants, which Jones' product controls, do not pose health and safety risks to the public. Again, it found that the risks associated with liquid sodium arsenate insecticides and the availability of safer alternatives far outweigh the limited benefits in controlling sweet-eating ants. 22/

In reaching its decision to cancel all registrations of inorganic arsenicals registered for non-wood-preservative uses, the EPA also noted that its preliminary determination to cancel had been sent to the United States Department of Agriculture ("USDA") and the FIFRA Scientific Advisory Panel ("SAP") for review and comment. 23/ The USDA notified the EPA that it does not have any objection to the EPA's proposed decision. The SAP waived scientific review and comment since it found that there

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21/ Notice, 53 Fed. Reg. at 24793.

22/ Notice, 53 Fed. Reg. at 24793.

23/ Notice, 53 Fed. Reg. at 24791. Submission to the USDA is required by FIFRA, § 6(b), 7 U.S.C. 136d(b), and to the SAP by §§ 6(b) and 25(d), 7 U.S.C. §§ 136d(b) and 136w(d).

were no scientific issues to consider with respect to the preliminary determination. 24/

Based upon the information before it, the EPA concluded that all registrations for sodium arsenate pesticides products not used as a wood preservative should be cancelled because of (1) the magnitude of the acute hazard to the public posed by the products, (2) the limited benefits of these products in controlling pests that pose no significant health or economic risks and (3) the availability of alternatives that provide similar benefits with negligible demonstrated risk. 25/ The EPA said that it had discussed with Senoret the use of child-resistant bait stations as a risk reduction measure short of cancellation but Senoret had said this alternative was unacceptable to it. 26/ The EPA finally held that in view of the risks of continued use of the product, it would not permit the continued sales, distribution and use of existing stocks beyond the date of cancellation. 27/

II. Sodium Arsenate Insecticides

The Notice covered several inorganic arsenical products registered for non-wood uses. The only ones for which objections were filed and are at issue in this proceeding, however, are the insecticides containing sodium arsenate used to control ants. The specific products are:

24/ Notice, 53, Fed. Reg. at 24791.

25/ Notice, 53 Fed. Reg. at 24794. The EPA also determined to cancel the registration for the bait product containing calcium arsenate, which product it found had not been manufactured or available for use for many years, and all registrations for arsenic trioxide pesticide products not used as a wood-preservative with certain exceptions. See supra, p. 6.

26/ Notice, 53 Fed. Reg. at 24794.

27/ Id.

Terro Ant Killer manufactured and formulated by Senoret Chemical Co., Inc. Terro Ant Killer contains 2.27% sodium arsenate in a sweet liquid solution and is used to control sweet-eating ants. It is sold in 1 fl. oz. and 2 fl. oz. bottles and packaged in a cardboard box to which is attached a strip of cardboard perforated into small squares. The directions instruct the user to put the product on the cardboard squares, and place the square with the product on it (hereafter called the "bait station") where ants are seen. 28/ The product is currently sold in bottles which contain a child resistant cap, requiring the person to push down on the cap and turn to open it. 29/

Jones Ant Killer manufactured and formulated by Jones Products, Inc. Jones Ant Killer contains 1.5% sodium arsenate in a sweet liquid solution and is also used to control sweet-eating ants. The product is marketed in 1 fl. oz. and 2 fl. oz. bottles. Both sizes contain an open plastic cup for use as the bait station for dispensing the product. 30/

FATSCO Ant Poison manufactured and formulated by FATSCO. FATSCO Ant Poison contains 3% sodium arsenate in a sweet liquid. The product is marketed in 1/2 oz., 3/4 oz. and a 2 oz. bottle. FATSCO also sells an ant cup for use as a bait station in dispensing the product. The label on the 1/2 oz. size bottle recommends use of pieces of cotton as ant baits. 31/

28/ Joint Stipulation; Senoret Exs. 67, 68; EPA Ex. 215.

29/ Senoret Ex. 30 (p. 4); Senoret Exs. 67, 68.

30/ Joint Stipulation; EPA Ex. 215.

31/ Joint Stipulation; EPA Ex. 215.

Ant Kill sold by Protexall Products, Inc., and containing 2.27% sodium arsenate in solution. The product is marketed in a 2 fl. oz. size. 32/

The above products are all used to control ants and will hereafter be collectively referred to as "sodium arsenate ant bait products."

The sodium arsenate in these ant products is in the pentavalent state (having the capacity to form 5 bonds with atoms). Arsenic is also found in the trivalent state (having the capacity to form 3 bonds with atoms). 33/ Pentavalent arsenic is less toxic than an equivalent quantity of trivalent arsenic. 34/

At least two different chemical formulations of sodium arsenate are identified in this proceeding. One is the formulation for Terro manufactured by Petitioner Senoret Chemical Co., the specifications of which are as follows:

SODIUM ARSENATE

(Arsenic acid, disodium salt; CAS 7778-43-0; Molecular Formula As-H-O4 .2Na; Molecular Weight 185.91)

This formulation is also known as "dibasic sodium arsenate." 35/

32/ The description of Ant Kill is taken from EPA Ex. 119 (pp. 4-5) (testimony of David Brassard). The label submitted with Mr. Brassard's testimony for Ant Kill is one showing 9.5% boric acid as the active ingredient. See EPA Ex. 215. This is obviously the wrong label as this product is not subject to the Notice. The label for the boric acid product contains no mention of a bait station but only instructs the user to use a few drops and it is assumed that the label for the sodium arsenate product reads the same.

33/ EPA Ex. 117 (pp. 16-17).

34/ Infra, p. 20.

35/ EPA Ex. 117 (p. 20); EPA Ex. 171.

The other formulation is that found in the product manufactured by Petitioner FATSCO, the specifications of which are as follows:

SODIUM ARSENATE
(Arsenic acid, sodium salt; CAS 7361-89-2;
Molecular Formula As-H_3-O_x .xNA; Molecular
Weight 302.88) 36/

It is assumed that Jones Ant Killer and Protexall's Ant Kill are similar to either Terro or FATSCO in their sodium arsenate chemical formulation. 37/

III. The Risks of Sodium Arsenate Ant Bait Products

The risk of sodium arsenate ant bait products emphasized by the EPA is of their acute toxicity, that is, the effects of a short term exposure such as ingestion of part or all of the contents of a bait station. Stated another way the risk can be described as that of acute poisoning. 38/ The EPA laid particular stress upon the number of acute poisoning incidents that have occurred as a result of the accidental ingestion of sodium arsenate ant bait products, and that the majority

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36/ EPA Ex. 117 (p. 20).

37/ Although, the EPA alludes to the two different formulations of sodium arsenate, it does not seek to distinguish them insofar as toxicity is concerned, nor does the evidence of record indicate any difference in toxicity. Health studies done on the two formulations are listed in EPA Exs. 169 and 170, submitted with Dr. Halls' testimony, but Dr. Hall drew no distinction between the two products.

38/ The American Association of Poison Control Centers for purpose of their reports define an acute exposure as a single, repeated or continuous exposure over a time period of less than 8 hours. EPA Ex. 134. Dr. Morgan defines acute poisoning as that resulting from the absorption of a large amount over a short period of time in contrast to chronic poisoning which is the absorption of lesser doses over a longer time interval. EPA Ex. 27 (p. 5).

of incidents have involved children. 39/ There are isolated instances in the record where workers and other persons have been exposed to arsenic over a period of time. There are also a small number of instances where persons have intentionally drank from a bottle. 40/ The risk created by the sodium arsenate ant bait products appear to involve an acute accidental exposure. I do not read the EPA's notice as directed against either the possible chronic risks created by the use of sodium arsenate ant bait products, or the small number of intentional exposures in the record, except insofar as they shed light on the toxicity of the products.

The accidental exposures to these sodium arsenate ant bait products have occurred despite warnings on the label that the product should be kept out of the reach of children and that it may be fatal if swallowed. If these warnings are not followed it is not because of any deficiency in the labeling itself. 41/ It could be argued, then, that these accidental poisonings result from the product being used negligently and not in accordance with label directions, as required by the Act. 42/

39/ Notice, 53 Fed. Reg. at 24789, 24792.

40/ See EPA Ex. 147 (pp. 3-4); EPA Ex. 1(pp. 52-56). In 1987, out of 1475 ant bait exposures reported to the American Association of Poison Control Centers, 41 (2.8%) were intentional exposures. Suicidal attempts accounted for 27, 1 was a misuse, 1 was a substance abuse and 12 were unknown reasons. EPA Ex. 133 (Table I-02A).

41/ See labels for the products in the Joint Stipulation and in EPA Ex. 215. I agree with Senoret's argument that Terro's labeling provides sufficiently clear instructions to the user to avoid unintended exposure. See Senoret's brief in support of proposed findings, etc. (hereafter " Initial Br.") at 60-61.

42/ See FIFRA, § 12(a)(2)(G), 7 U.S.C. 136j(a)(2)(G), which makes it unlawful to use any registered pesticide in a manner inconsistent with its labeling.

This, in itself, is not a defense to cancellation. Even though a product's label may contain adequate instructions and warnings for the user, it may still be cancelled whenever the risk arising from its use is great enough to cause unreasonable adverse effects on the environment. This is borne out by the statutory language and its legislative history.

The statutory requirements for cancelling a pesticide are that either it does not comply with the requirements of the Act or, when used in accordance with widespread and commonly recognized practice, it generally causes unreasonable adverse effects on the environment. 43/ The pertinent requirements for registering a pesticide are that it will perform its intended function without unreasonable adverse effects on the environment and that when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment. 44/ Unreasonable adverse effects on the environment are defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 45/

Stearns Electric Paste Co. v. EPA, 461 F.2d 293 (7th Cir. 1972), one of the first cancellation cases under FIFRA, is instructive in interpreting this language. In that case, the facts were similar to those here. The EPA sought the cancellation of a rat and roach poison used in

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43/ FIFRA, § 6(b), 7 U.S.C. 136d(b).

44/ FIFRA, § 3(c)(5), 7 U.S.C. 136a(c)(5).

45/ FIFRA, § 2(bb), 7 U.S.C. 136 (bb).

the home because of the accidental poisonings that occurred particularly to children. The case was brought under FIFRA before it was amended and rewritten by the Federal Environmental Pest Control Act of 1972. 46/ The statute then provided that an insecticide was misbranded if it was injurious when used as directed or in accordance with commonly recognized practice. 47/ The EPA sought to cancel the product on the ground that the product was misbranded within the meaning of the Act. 48/ The court disagreed. It construed the statute as primarily a regulation of labels and said that a necessary assumption is that the general public does heed warnings. Accordingly, the court rejected a test of misbranding predicated on total illiteracy or universal disregard of instructions. 49/

Stearns Electric Paste Co., is cited by Senoret, but the case is no longer in point since the statute considered by the court was superseded by the legislation enacted in 1972 . 50/ One of the changes to FIFRA considered by Congress in amending the statute in 1972, was a provision in the Senate bill classifying a pesticide as misbranded if "when used

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46/ Pub. L. No. 92-516, 86 Stat. 973 (1972). Prior to passage of the Federal Environmental Pest Control Act of 1972, the statute was codified at 7 U.S.C. §§ 135-135k. By the 1972 Act these provisions were superseded by 7 U.S.C. §§ 136-136u. For provisions of former 7 U.S.C. §§ 135-135k see 2 United States Code (1982 Ed.) at 104-109. The EPA was first given authority to cancel a pesticide in 1964. See Pub. L. 88-305, 78 Stat. 190 (1964).

47/ See former FIFRA § 135(Z)(2)(g), supra, n. 46.

48/ Stearns Electric Paste Co., 461 F.2d at 301.

49/ Stearns Electric Paste Co., 461 F.2d at 310.

50/ Senoret's Reply Br. at 3, 5. See supra, n. 46.

in accordance with the requirements of the Act or commonly recognized practice" it causes unreasonable adverse effects on the environment. On consideration of the bill in conference, this provision was deleted, and the language shifted to FIFRA §§ 3 and 6. The explanation was as follows:

> The conferees do not believe that a manufacturer should be subjected to criminal penalties for a "misbranding" which is beyond his control. The conference substitute shifts this language to Section 3 and Section 6. Thus, although no criminal penalties are applicable, the Administrator will have the authority to deny registration or cancel where there is a widespread and commonly recognized practice of using a pesticide which generally causes unreasonable adverse effects on the environment. 51/

In short, registration and continued use was no longer to be dependent upon whether the labeling contained adequate directions for use and warnings as the pre-1972 FIFRA was construed by the court. The adverse effects of the product in actual use was now also to be considered.

Unreasonable adverse affects require an evaluation of both the risks and the benefits. On the risk side the question to be decided is what are the risks when this product is used in accordance with widespread and commonly recognized practice.

51/ See H.R. Conf. Rep. No. 92-1540, 92d Cong. 2d Sess. 30-31 (1972).

A. The Toxicity of Sodium Arsenate Ant Bait Products

1. Estimation of Acute Toxicity Derived from Animal Data

One measure of the acute toxicity of a substance is the acute oral LD_{50}, defined as the statistically derived estimate of the single oral dose that would cause 50% mortality to the test population under specified conditions. 52/ LD_{50} is expressed in the ratio of miligrams (or grams) of substance ingested to the weight of the animal (in kilograms). It is to be noted that it is a measure of a dose that causes death and not of the dose at which non lethal adverse effects can occur.

Senoret relies on an LD_{50} study done on rats showing that the LD_{50} for Terro in rats is 5,850 mg/kg. 53/ This would place it in the EPA's toxicity category IV, the least toxic category. 54/

The EPA claims that the value found by Senoret understates the toxicity of Terro, because a study done by the National Academy of Sciences had shown that the rat metabolized arsenic differently than other animals and might be less sensitive to arsenic than humans. The National Academy of Sciences recommended, instead, that the hamster be used. 55/ The EPA, accordingly, ran LD_{50} tests on both hamsters and rats using sodium

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52/ 40 C.F.R. § 152.3(e). The oral LD_{50} is used because there is no evidence of any risk of dermal or inhalation poisoning from these ant bait products.

53/ Senoret's proposed finding of fact (hereafter "PF") No. 4, citing Senoret Ex. 75, which is a revision of EPA Ex. 29, but reports the same LD_{50}.

54/ 40 C.F.R. § 156.10(h)(1).

55/ EPA Ex. 1 (p. 16); EPA Ex. 5 (p. 110).

arsenate heptahydrate as the test substance and both weanling and adult rats and hamsters as the test animals. The tests resulted in an LD_{50} of 54 mg/kg for the adult male hamster compared to an LD_{50} of 144 mg/kg for the adult female rat, thus showing that sodium arsenate is more toxic to the hamster than to the rat. 56/ Using the value for the adult male hamster and adjusting it for the fact that Terro contains 2.27% sodium arsenate, Mr. Blondell, the EPA's expert health statistician, derived an LD_{50} for Terro of 2379 mg/kg. 57/ This would place Terro in EPA category III instead of the less toxic category IV, that would apply under Senoret's LD_{50}. 58/

Besides the EPA's rating system, there is also another system for classifying the toxicity of chemicals, which is used by clinical toxicologists. Under this system, Terro with its value of 2379 mg/kg, or 2.379 g/kg, would be placed in Class 3 (moderately toxic). Between 1 ounce and 1 pint would be considered a probable lethal dose for a 70 kg

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56/ EPA Ex. 1 (pp. 15-16); EPA Ex. 6 (Tables 1 and 2). The values are the 14-day LD_{50}. The lower the dose per kilogram of body weight found to cause death, the greater is the toxicity of the product.

57/ EPA Ex. 1 (p. 20). The test showed an LD_{50} of 91 mg/kg for the sodium arsenate heptahydrate, which value was multiplied by 0.596 to obtain 54 mg as the value of the sodium arsenate moiety. See EPA Ex. 6. Dividing this value by .0227 yields 2379 mg of Terro as the equivalent of 54 mg of sodium arsenate. The values for the three other sodium arsenate products, similarly computed were:

Jones Ant Killer - 3600 mg/kg
FATSCO Ant Poison - 1800 mg/kg
Protexall Ant Kill - 2379 mg/kg

58/ 40 C.F.R. § 156.10(h)(1).

(150 lb.) person. 59/ In the case of Terro, a single dose of one ounce could be fatal. 60/

Senoret claims that the EPA was arbitrary in rejecting the lower toxicity rating based on the rat. It points out that the National Academy of Sciences study which concluded that the rat was not a suitable test animal for determining the toxicity of arsenic to humans was based on testing done with trivalent arsenic. 61/

There appears to be no dispute that trivalent arsenic is much more toxic than an equivalent quantity of pentavalent arsenic. 62/ Indeed, this difference is recognized in the National Academy of Sciences study itself. 63/ The peculiar metabolic characteristic noted in the rat, however, to bind arsenic in the hemoglobin of the red cells and thereby slow down the release of arsenic to tissue sites where it would be harmful, appeared to relate to arsenic in general. Thus, it was reasonable for

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59/ EPA Ex. 36; Senoret Ex. 75.

60/ The estimated median lethal dosage for a Class 3 toxic material is between 0.5 - 5 grams/kg. EPA Ex. 36 (p. II-4). An ounce of Terro weighs 36.26 grams. EPA Ex. 39. Dividing 36.26g by 70 kg, would yield about 0.5 g/kg., or on the borderline between an estimated lethal dose for a moderately toxic and a very toxic poison. See also EPA Ex. 137, § 6.8A, the POISINDEX [R] Information System, rating as "Moderately Toxic" a substance with a probable oral human lethal dose of between 30-400 ml. One ounce of Terro is equal to 29.6 ml., again on the borderline between a moderately toxic and a very toxic poison. EPA Ex. 39.

The same Moderately Toxic rating would apply to the other three products as well. EPA Ex. 1 (p. 20).

61/ Senoret's Initial Br. at 11.

62/ See e.g., EPA Ex. 5 (pp. 129, 145); EPA Ex. 117 (p. 24); EPA Ex. 135 (pp. 133, 135); EPA Ex. 137 (§ 6.3.D.); Senoret Ex. 69 (pp 1-2); Tr. 74-75.

63/ EPA Ex. 5 (pp. 120, 133-35).

the EPA to assume from the observations made in the study that the hamster gave more reliable results for predicting the toxic effect of sodium arsenate on humans than did the rat. 64/

Senoret also asserts that the EPA LD_{50} test was flawed because sodium arsenate heptahydrate was used and the quantity of sodium arsenate obtained by taking the value of the sodium arsenate moiety in the compound. It is to be noted, that the LD_{50} value of 144 mg/kg so obtained for the adult rat does not seem to materially differ from the LD_{50} for adult rats found in Senoret's study. 65/

Finally, Senoret also argues that the EPA contrary to its own guidelines did not use "young" adult hamsters in its test. 66/ It is to be noted that Senoret's study states only that female rats were used and while it is assumed they were adults, their ages were not specified. 67/ Therefore, it is not all clear where Senoret would draw the line between a young adult and an adult. In any event, since the adult rat LD_{50} obtained in the EPA's study agreed closely with that found in Senoret's

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64/ Use of the hamster had at least the advantage of not confounding the test results with the problem created by the metabolic difference observed in the rat.

65/ Senoret's study showed an LD_{50} for Terro of 5850 mg/kg for the adult female rat. Senoret Ex. 75. Adjusting for the fact that 2.27% of Terro is sodium arsenate that would produce a value of 133 mg/kg of sodium arsenate compared to the value of 144 mg/kg found in the EPA's study. See EPA Ex. 1 (p. 17)

66/ Senoret's Br. at 11, 13.

67/ See Senoret Ex. 75.

study, whatever differences there might have been in ages did not appear to materially affect the results. 68/

It is accordingly found that the LD_{50} obtained for the adult male hamster of 54 mg/kg, which translated for Terro means an LD_{50} of 2379 mg/kg, is more reliable for estimating the risk to humans than the LD_{50} obtained by Senoret from its rat study.

In using animal data to estimate human toxicity, a generally accepted practice appears to be to allow for a ten-fold margin of safety, that is, to assume that humans are ten times more sensitive than animals to a poison. 69/ The LD_{50} is a measure of lethality but in the treatise "Clinical Toxicology for Commercial Products", it is also stated that a clinically significant illness may be expected after doses of about one-tenth the probable lethal dose. 70/

Terro and the other sodium arsenate ant bait products are used by putting a small amount on a bait station which is then placed in the vicinity where the ants are seen. In evaluating the risk created by the sodium arsenate products, two souces of exposure should be considered, the

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68/ Senoret also criticizes the EPA for departing from EPA protocol in using weanling rats and weanling hamsters. Br. at 11. The values for these animals are not relied on for determining the LD_{50}.

69/ EPA Ex. 39; Senoret Ex. 75. The reference in these exhibits is to data derived from Senoret's rat studies, but in the absence of evidence to the contrary, I assume that the same margin of safety applies to human risk estimates based on animal data generally.

70/ EPA Ex. 36 (pp. II-3 to II-4).

bottle and the bait station. The great majority of exposures in the record in this case were accidental exposures to the bait station. 71/

Mr. Blondell calculated the following dosages for each of the four sodium arsenate ant bait products, assuming the contents of the entire bottle in which it was sold were ingested.

Brand	Size of Bottle	Amount of Sodium Arsenate	Dosage mg/kg (7.4 kg. 6 mos. child)
Terro	1 oz.	823 mg.	111.2 mg/kg
Jones	1 oz.	516 mg.	69.7 mg/kg
Protexall	2 oz.	1613 mg.	218 mg/kg
FATSCO	1/2 oz.	533 mg.	72 mg/kg

All of these doses exceed the 54 mg/kg LD_{50} found for sodium arsenate and demonstrate that a bottle of any of the sodium arsenate ant bait products is indeed toxic. 72/

Turning to the bait station, where the largest number of exposures occur, the little cardboard piece sold as a bait station with Terro will

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71/ There were 269 cases of arsenic and bait exposures reported to the Blodget Regional Poison Control Center during the period of January 1, 1985-August 16, 1988. In 28 of these cases (10.4%), the bottle was identified as the source. EPA Ex. 8.

72/ EPA Ex. 1 (pp. 25-26). The Terro calculation is based upon a specific gravity of 1.225 grams/ml and the fact that it contains 2.27% sodium arsenate. One ounce is equivalent to 29.6 ml. See EPA Ex. 29 (p. 2). Thus, 29.6 x 1.225 x .0227 = .823 grams or 823 mg. The Jones calculation, similarly done, is based upon a specific gravity of 1.163 and the fact that it contain 1.5% sodium arsenate. See EPA Ex. 40. The dosages for Protexall and FATSCO are estimated by assuming that they have approximately a specific gravity of 1.2 gr/ml.

For a child under 3 years weighing between 10 and 15 kg, see EPA Ex. 39 (p. 2), the dosage would still greatly exceed the one-tenth margin of safety.

hold approximately 1 ml of Terro. 73/ As the EPA points out, however, Terro is often used with bait stations other than the cardboard squares, such as bottle caps, tinfoil, paper, food such as crackers, jar lids and cotton balls. 74/ It is not known how much Terro was contained in these bait stations. The instructions for Terro do not prescribe any specific amount to be placed on the bait station (such as a 1/4 teaspoon), nor do they prohibit the use of other materials as bait stations. 75/ Presumably they could hold more or less, but for purposes of this case it will be assumed that they hold at least 1 ml, and very likely more. The EPA argues that 2.5 ml is a reasonable estimate for the amount present on a

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73/ Various values are given for the amount a bait station can hold. Scientific Associates, in data submitted to the EPA on behalf of Senoret originally estimated 2 ml. EPA Ex. 38. In a revision of this data, they changed it to 0.6 ml. Senoret Ex. 75. Dr. Kingston as a result of his tests estimated between 0.6 ml and 1 ml. Senoret Ex. 72 (p. 3). Mr. Blondell took 2.5 ml, halfway between the 2 ml first estimated by Scientific Associates and the 3 ml estimated by Senoret's President, Mr. Roberts. Judging from Dr. Kingston's testimony, it would appear that about 1 ml is the amount that can be placed on a bait station using reasonable care without it spilling off. Tr. 2083-2085, 2252-2253. The EPA's estimate of 2.5 ml is admittedly too high. Initial Br. at 37.

74/ Of the 187 cases reported to the Blodgett Regional Poison Control Center as involving children exposed to Terro bait stations, the cardboard was not used in 29% of the cases. EPA Ex. 1 (p. 23); EPA Ex. 8. It should be noted that only six cardboard squares are supplied with a one ounce bottle which holds 29.6 ml, and 9 cardboard stations are supplied with a 2 ounce bottle. Senoret Exs. 67 and 68. It is not at all unlikely, then, for a user to run out of cardboard and turn to other material for a bait station.

75/ Senoret Exs. 67 and 68. In fact Senoret has recommended to their customers that a bottle cap or wax paper be used, as well as recommending peanut butter and bacon grease for grease-eating ants. EPA Ex. 1 (p. 24).

bait station. 76/ This does not on its face appear to be unreasonable as an average value for assessing the risk to a bait station, given the different materials that may be used.

As to the risk created by the bait station, the EPA supplies the following data regarding the amount of sodium arsenate ingested, assuming that 7.4 kg six-month old child consumed 2.5 ml of the product: 77/

Terro:	9.22 mg/kg
Jones:	8.1 mg/kg
Protexall:	9.0 mg/kg
FATSCO:	12.0 mg/kg

Using the hamster 54 mg/kg LD_{50} for sodium arsenate, these values do not meet the one-tenth margin of safety which toxicologist have said should be used in transferring animal data to humans.

If the 1 ml cardboard bait station for Terro were consumed by a 6 months old child, the child would have taken a dose of about 3.78 mg/kg which would be less than one-tenth the LD_{50}. 78/

76/ EPA Initial Br. at 49. It is to be noted that the Jones bait station, which is a plastic cup holds approximately 60 mg of sodium arsenate. Joint Stipulation, Par. 14; EPA Ex. 40. This would be between 3.1-3.5 ml. EPA Ex. 40. Jones' calculation of 2.2 ml, post-hearing brief at 5, is inconsistent with EPA Ex. 40, and the stipulated facts.

77/ EPA Initial Br. at 37.

78/ For basis of calculations, see supra, p. 23, n. 72. Following the same calculations, one ml x 1.225 grams/ml equals 1.225 grams x 2.27% = 0.028 grams of arsenic or 28 miligrams of arsenic. 28 mg/7.4 kg equals 3.78 mg/kg.

It is to be noted that animal lethality data relating to sodium arsenate, however, is only a crude measure in assessing the risk to humans because of differences between animal species (including humans) in the way they handle arsenic and their relative sensitivity to it. 79/

Aside from the LD_{50} there are also references in the record to a minimum lethal dose ("MLD") obtained from animal data, namely the lowest dose to cause death or illness. 80/ The fact that a concentration is lower than the minimum lethal dose may be some evidence of the lack of toxicity of the product. It is less persuasive as a measure of the toxicity of the product because the statistical reliability of the value for purposes of assessing the probability that the dose will cause death or illness is not shown.

In addition to animal data, the EPA also relies also on actual human poisoning data to estimate the risk of sodium arsenate ant bait products to humans. 81/

2. Estimations of Acute Toxicity Based on Human Data

The EPA used three cases, two of them apparently involving intentional ingestion, to extrapolate the following potentially lethal doses for a one year old child:

79/ Tr. 948-49.

80/ See e.g., Mr. Blondell's discussion of the study done on cats. EPA Ex. 1 (p. 19). The lowest dose to cause mortality in cats was 23 mg/kg, while the lowest dose to cause death in the hamster was 30 mg/kg (after removing the heptahydrate). EPA Ex. 6.

81/ EPA Initial Br. at 36.

Terro and Protexall:	10 ml - 18 ml
FATSCO:	8 ml - 14 ml
Jones:	15 ml - 27 ml

This would represent between approximately 1/3 and 3/5 of a one ounce bottle of Terro and Protexall, 1/2 to almost an entire 1 ounce bottle of Jones and 1/4 to 1/2 ounce of FATSCO which is sold in a 1/2 ounce bottle. 82/

One case involved a 57 year old woman weighing 175 lbs. (79.5 kg) who had intentionally ingested 60 ml of FATSCO ant poison. The women also had a history of asthma, diabetes, and an undefined abnormality of renal (kidney) function. She was treated for arsenic poisoning and subsequently died. Postmortem confirmed arsenic as the cause of fatality. 83/

The second case was the intentional ingestion by a 32 year old, 65 kg male, who drank 120 ml of Terro (4 one-ounce bottles) in a suicide attempt. This person exhibited symptoms of severe arsenic poisoning but eventually recovered. Dr. Litovitz considered this an appropriate case for estimating a fatal dose because he had a life-threating exposure and

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82/ EPA Initial Br. at 26-32. The one year old child is assumed to weigh 10 kg. See EPA Ex. 37; EPA Ex. 7 (p. 18). An ounce is equivalent to about 30 ml, a tablespoon to 15 ml, and a teaspoon to 5 ml. EPA Ex. 7 (p. 18).

83/ EPA Ex. 7 (pp. 17-18); EPA Ex. 186 (Ex. C); EPA Rebuttal Ex. 1 (p. 9); Tr. 1254-55. The patient had extremely high levels of arsenic in her urine. The EPA admits that the patient's health problems could have exacerbated her toxic response to the FATSCO ant poison. Reply Br. at 15. It goes on to argue that children exposed to Terro may have similar health problems which might also make them more susceptable. The EPA's argument is subject to the same flaw as the minimum lethal dose, supra p. 26. It is impossible to tell whether we are dealing with a remote occurrence or something that is likely to happen with some frequency.

would have died had it not been for medical intervention. Extrapolating from the amount the adult had ingested, Dr. Litovitz estimated that 18 ml of Terro would be a potentially lethal dose in a 10 kg, one-year old child. 84/

The third case cited by EPA is the accidental death of a five year old child who Mr. Blondell estimated had drank from the bottle of Terro a dose estimated to be equal to 30 mg/kg. on the assumption that the child drank 1/3 of the contents of a 2 ounce bottle. 85/ Since a 2 ounce bottle contains 59.2 ml, one-third of the contents would equal about 20 ml. Adjusting for the difference between a 5 year old, 18.4 kg child and a one year old 10 kg child, this would be equal to a dosage of about 10.8 ml or over a 1/3 of a one ounce bottle for a one year old child. 86/

The above estimate of lethality based on human poisonings are clearly very rough. Nevertheless, if one accepts the estimate that a significant illness may result from one-tenth the probable lethal dose, they do

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84/ EPA Ex. 7 (pp. 17-19, 23-24); Tr. 1255. Dr. Litovitz considers her estimate as probably an over-estimate of the potentially lethal dose because the spontaneous vomiting by the adult soon after ingestion probably removed much of the sodium arsenate. One ounce of Terro has been calculated to contain 0.82 grams of sodium arsenate or 820 mg. EPA Ex. 39. Four ounces then would amount to 3280 mg of arsenic. Since the adult male weighed 65 kg, the potentially lethal dose would be equivalent to 51 mg/kg. Mr. Blondell noted that this dose was close to the 54 mg/kg for hamsters and considered it corroboration of the hamster as a better animal for testing human lethality than the rat. EPA Ex. 1 (p. 39).

85/ EPA Ex. 1 (pp. 38-39); EPA Ex. 1A; Tr. 327-329. The conclusion that this child died from drinking Terro ant poison is supported by the death certificate. EPA Rebuttal Ex. 1 (pp. 1-5).

86/ See EPA Ex. 1 (p. 38); EPA Ex. 7 (p. 18); EPA Ex. 39.

suggest that exposure to the bait station of any of these products could produce significant illness. 87/

We turn next to consider what evidence of risk created by the bait station and bottle is disclosed by the human exposure data from the poison control centers and other sources.

3. Acute Toxicity Data Based on Reported Human Exposures

Since 1983, the American Association of Poison Control Centers ("AAPCC") has been collecting data on poison exposures reported to it. By 1987, the data collection system had grown to where 63 poison control centers throughout the United States serving a population of 137.5 millions were participating in the system. This represented about 57% of the United States population. 88/ By "exposure" is meant that the person came into contact with a poison. Not all exposures necessarily result in a poisoning. 89/

AAPCC began reporting specifically on arsenic ant bait exposures in 1984. In 1987, 1475 cases of exposure to Terro or Jones arsenical ant baits were reported to the AAPCC, which represented about 1/8 of 1% of total human poison exposures reported. Only five of these exposures

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87/ See EPA Ex. 36 (p. II-3). The Jones bait station holds between 3.1 and 3.5 ml. EPA Ex. 40. It is estimated that in the case of Protexall and FATSCO, where no specific bait station is supplied, approximately 2.5 ml will be dispersed in a single application.

88/ EPA Ex. 131 (pp. 479-481).

89/ Tr. 632.

were chronic and the rest were acute. 90/ Deleting some 11 cases, which were acute exposures where some other substances as well as sodium arsenate was implicated, an analysis of this data shows that nearly all of these exposures (97.6%) were accidental, and 1396 cases (95.4%) involved reported ingestion of an arsenic ant bait. Children under six were involved in 1251 (85.5%) of the reported exposures. 91/

Much of the controversy in this case stems from how serious should these exposures be regarded.

Symptoms and signs of acute arsenic poisoning generally appear within 30 minutes to one hour, but may be delayed up to 10-12 hours after ingestion if the arsenic is in solid form or ingested with food. The usual initial symptoms of arsenic poisoning are those due to gastroenteritis (vomiting, diarrhea, crampy abdominal pain). The patient may also suffer from chills, fever, headache, and nervousness. Bleeding from the gastrointestinal tract may also be seen on occasion.

If arsenic is absorbed into the lining of the blood vessels, damage can result in the form of leakage or "third spacing" of fluid from the blood vessels into the other tissues, leading to low blood pressure,

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90/ EPA Ex. 7 (pp. 9-10). The data for Jones and Terro was taken from EPA Ex. 133 (Table I-01A). Total exposures are from EPA Ex. 131 (p. 480). Acute exposure is defined in the reports as a single, repeated or continuous exposure occurring over a time period of less than 8 hours. EPA Ex. 134.

91/ EPA Ex. 133 (Tables I-01B, I-02B, I-05B, I-12B). The percentages differ slightly from Dr. Litovitz's (EPA Ex. 7 (p. 10)), because they do not include the 11 exposures where another substance was also involved. Of the children under six years of age, 283 were less than one year of age, 540 were one-year olds and ten were children of an unknown age under six years of age. EPA Ex. 133 (Table I-12B).

shock, and death if lost fluids and electrolytes are not adequately and promptly replaced. Third spacing results in a decrease in urine output because the leaked fluid is not eliminated by the kidney in the usual manner.

The heart may also be affected, resulting in abnormalities in the electrical activity of the heart, and even in ventricular arrhythmias or cardiac arrest in some cases. Pulmonary edema from capillary leakage or from respiratory muscle weakness may occur, and acute respiratory failure can result from the severe weakness of the respiratory muscles.

Diminishing kidney function or renal failure is another serious effect which may result from acute arsenic poisoning. Liver injury can also occur, and central nervous system effects, including toxic delirium, coma, and convulsions, may ensue. 92/

In addition to the above symptoms, expert witnesses for the EPA testified that there can be delayed adverse effects from acute poisoning with sodium arsenate such as peripheral neuropathy, i.e., injury to peripheral nerves resulting in decreased sensation, painful or numb/tingley sensations, and these can also result muscle weakness or paralysis. Other delayed effects can include depression of the blood-forming bone marrow (resulting in anemia with or without decreases in the production of other blood cells and dermal manifestation.) 93/

92/ See EPA Ex. 7 (pp. 14-15); EPA Ex. 27 (p. 6); EPA Ex. 117 (pp. 18-19); EPA Ex. 184 (pp. 4-5); EPA Ex. 192 (p. 8).

93/ EPA Ex. 7 (p. 15); EPA Ex. 117 (p. 19); EPA Ex. 147 (pp. 6-7); EPA Ex. 192 (pp. 8, 18-19).

Symptoms of acute poisoning were observed in some of the actual cases of ingestion of sodium arsenate. 94/ The EPA's experts, however, in evaluating the toxicity of a sodium arsenate ingestion also relied on the scientific literature reporting on the toxicity of trivalent arsenic and the conversion of pentavalent arsenic to trivalent arsenic in the body. Thus, Dr. Litovitz states that sodium arsenate, a pentavalent arsenic compound, is converted in the body to the more toxic trivalent arsenite. 95/ This is not to say that sodium arsenate may not be toxic in its own right. 96/ It is clear, nevertheless, that the toxicity of sodium arsenate described by the EPA experts is related to this conversion of pentavalent arsenic to trivalent arsenic in the human body, a conclusion that is also reached by some of the scientific articles relied by the experts. 97/

The phenomenon of the conversion of pentavalent arsenic to trivalent arsenic in the human body is not clearly understood and is the subject of

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94/ EPA Ex. 7 (pp. 17, 23-25); EPA Ex. 8.

95/ EPA Ex. 7 (p. 14).

96/ Thus Dr. McCoy stated that "[a]rsenate itself seems to interfer with the energy steps, the utilization of oxygen, the energy-storing steps in the oxidate phosphorylation system of the body. So its ability to use oxygen, to store energy, for whatever cellular purpose, is interrupted by arsenate by interferring with the phosphate type formations." Tr. 1103.

97/ See e.g., the POISINDEX[R] Substance Identification, EPA Ex. 137 (and Senoret Ex. 20) at §§ 6.3.D and 6.8.A; and the article "Arsenic Poisoning" by W.L. Schoolmeister and D.R. White, EPA Ex. 136 and Senoret Ex. 16 at p. 199.

debate among scientists. For example, Dr. Litovitz was of the opinion that there is a significant conversion of pentavalent arsenic to trivalent arsenic in the human body. 98/ On the other hand, Dr. William Banner, one of Senoret's expert witnesses was of the opinion that the amount of arsenate converted to arsenite was not significant enough to cause a clinical problem. 99/ Dr. McCoy summed up the state of knowledge generally, admitting that the in vivo interconversion of arsenate and arsenite was not fully understood and the quantity of arsenate converted to arsenite in the body of a human was unknown. 100/

This medical controversy over the toxicity of sodium arsenate, particulary if the exposure has been to a bait station, must be borne in mind in evaluating the opinions of the experts as to the toxic implications of the exposure.

Taking the 1987 AAPCC report as the most complete and comprehensive, the following is shown:

98/ Tr. 1297.

99/ Senoret Ex. 12 (p. 2); Tr. 1537-38. Contrary to what the EPA claims (Reply Br. at 44), there is some support in the record for Dr. Banner's assumptions that the pentavalent forms of arsenic are rapidly excreted from the body. See EPA Ex. 196 (pp. 86, 107); EPA Ex. 135 (p. 139). On the other hand, Dr. McCoy thought that even though sodium arsenate is rapidly excreted and there is a considerable amount immediately following exposure, enough possibly remains in the body to be toxic. Tr. 1094-95.

100/ Tr. 941, 1122. Dr. McCoy did state, however, that some studies indicated that the conversion of sodium arsenate to sodium arsenite could be as great as 25% of the sodium arsenate ingested. Tr. 1131.

A total of 1464 cases were reported of exposures to Terro or Jones where, except in one instance, the ant killer was the only product involved. Of these 1464 cases, 1429 (97.6%) were accidental, 34 (2.3%) were intentional, and one was from an adverse reaction, i.e., an allergic or idiosyncratic reaction. Almost all these cases (99.7%) were acute exposures. 101/

Of these 1464 exposures, 1161 (79.3%) were reported as having no effect. By this is meant that the patient developed no symptoms as a result of the exposure. 102/

It can be seen, then, that in the majority of cases reported to the poison control centers no poisoning appears to have occurred. In the remaining accidental exposures where symptoms did occur, 127 were reported as having a minor effect, twelve as a moderate effect and one as a major effect. Of the intentional exposures 12 were reported as having a minor, moderate or major effect. 103/

It is, however, the EPA's contention that the evaluation of risk simply on the basis of whether or not symptoms were manifested does not tell the whole story. The presence of unusually high arsenic levels in

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101/ EPA Ex. 133 (Tables I-01B, I-02B, I-04B); EPA Ex. 134 (p. 2). Five were reported as chronic exposures. The cases involved exposure to Jones or Terro. EPA Ex. 7 (p. 10).

102/ EPA Ex. 133 (Table I-16B); EPA Ex. 134 (p. 4). Of those reported as having no effect, 893 (61%) were treated in a non-health-care facility. Id.

103/ EPA Ex. 133 (TAble I-16B). The one accidental case listed as having a major effect involved an 18-month old child who drank from a bottle, and should be classified as a case with a moderate effect. Tr. 1242-46.

the body in the absence of symptoms must also be considered. 104/ Data compiled by the Blodgett Regional Poison Center for arsenical ant bait poisonings for the period from January 1, 1985 through August 16, 1988, discloses that even though the cases are asymptomatic when reported, many of the patients may still have abnormally high levels of arsenic in their urine. 105/

The Blodgett Regional Poison Center ("Blodgett") is one of approximately 35 centers certified as a regional poison control center by the American Association of Poison Control Centers. Blodgett operates 24 hours a day, every day of the year. The geographical region served by Blodgett is a 44,544 square mile area which includes 65 of Michigan's 83 counties. This region has a population of 3,219,923 and contains 112 hospitals having a total of approximately 14,882 hospital beds. Based on the number of patient calls taken, Blodgett is the 13th largest poison center in the United States. The center is staffed by Registered Nurses who have comprehensive training in toxicology. These "Specialists in Poison Information" take poison calls from the general public as well as medical professionals. Approximately 75% of these calls involve a "patient" exposure to a poison. The remaining 25% are non-patient calls requesting information about poisons. Sixty-five percent of the "patient"

104/ EPA's Initial Br. at 65-89.

105/ EPA Ex. 8. The Blodgett cases are also reported on the AAPCC reports under case Nos. beginning with 036. While there is some discrepancy in the numbers, it does not appear to affect the conclusions which are drawn from the data here. See Tr. 1113-1117.

three fourths of these patient exposure calls are determined to be either nontoxic or minimally toxic and are managed at the site of exposure, typically in the home. Approximately 7% are judged to be serious enough to be referred to a health care facility. Another 10.5% of the calls originate from a health care facility and typically already involve med-medical management. 106/

During the period January 1, 1985 - August 16, 1988, Blodgett received 269 calls regarding exposures to sodium arsenate ant bait products, broken down by brand as follows:

Terro	249 calls	(92.5%)
FATSCO	15 calls	(5.6%)
Jones	4 calls	(1.5%)
Unknown	1 call	(0.4%) 107/

Of these exposures, 262 (97.4%) were accidental, 6 were intentional suicide attempts and one was a substance abuse. 108/ The bait station was the source of exposure in 73% of the cases, and the bottle the source of exposure in 10.4% of the cases, as shown by the following data:

106/ EPA Ex. 192 (p. 3).

107/ EPA Ex. 202. The tables shown in EPA Exs. 200-207, are also contained in EPA Ex. 8.

108/ EPA Ex. 202.

Bait Station:	
Cardboard	131 cases (48.7%)
Other	67 cases (24.9%)
Bottle	28 cases (10.4%)
Other & Unknown	43 cases (15.9%)
	269 cases 109/

In terms of age of patient, 245 of the exposures (91.1%) involved children under 6. 110/

If these exposures are analyzed in terms of those reported as manifesting symptoms, only 21 out of the 269 were reported as symptomatic. When these symptomatic cases were further analyzed, most were cases where vomiting was only the symptom. 111/

109/ EPA Ex. 206. The other bait stations consisted of bottle caps, paper, cotton balls, food items and a card. The percentage for the bait station other than cardboard differs slightly from Dr. McCoy's testimony so it is possible that a few of the items listed in EPA Ex. 206 may not be considered bait stations. See EPA Ex. 192 (p. 15).

110/ EPA Ex. 204. The fact that children under six constitute most of the calls seems to be true of all exposure cases reported to Blodgett. See EPA Ex. 195 (p. 22), where it was stated 64.7% of the poisoning cases involved children under 6. That was still a much lower proportion of exposures than was the case with the sodium arsenate ant bait products.

111/ EPA Ex. 8. Four of the symptomatic cases, Nos. 1, 2, 25 and 57, were suicidal. Sixteen out of the 17 accidental cases, Nos. 15, 16, 22, 23, 26, 37, 43, 45, 62, 73, 77, 120, 202, 210, 211 and 213, involved children under 6. Three of the cases, Nos. 16, 43, 57 involved FATSCO and the rest were Terro.

Contrary to what Senoret argues, this data in itself is cause for concern as to the risk of these sodium arsenate ant baits. 112/ It is the EPA's position, however, that the manifestation of symptoms as reported to the poison control centers is not the full measure of risk.

Dr. McCoy, a well qualified toxicologist and chairman of the Division of Toxicology at Blodgett, stated that in order to most accurately assess exposure to any arsenic containing product, the most reliable way is to measure the actual concentration of arsenic in body fluids or tissues. One common way to make such a measure is to measure the level of arsenic in the urine. The 24 hour urine collection has been recommended over spot (a single voiding) urine specimen. In a potentially acute toxic exposure, however, the 24 hour collection may delay appropriate treatment permitting the toxic action of arsenic to progress. Early appropriate treatment reduces the toxic effects due to arsenic exposure and decreases the mortality associated with the episode. Accordingly, Blodgett follows a treatment protocol in which a spot urine is collected 2 to 4 hours post exposure. If a value greater than 200 micrograms of arsenic per litre (200 mcg/L) is shown, Blodgett considers that there has been an abnormal exposure to arsenic and recommends treatment accordingly. 113/

112/ See Senoret's Initial Br. at 28-29.

113/ EPA Ex. 192 (pp. 11-12). For definition of spot urine, see Tr. 1178. The spot urine does not tell how much sodium arsenate was actually ingested, but does indicate that more than normal amounts of arsenic are in the body. See Tr. 733. On the validity of urine tests as an indicator of arsenic poisoning generally, see EPA Ex. 27 (p. 7), the treatise "Recognition and Management of Pesticide Poisoning," by Dr. Donald P. Morgan, where it is stated that measurement of 24-hour urinary excretion of arsenic (micrograms per day) is probably the best way to confirm excessive absorption.

Dr. Litovitz also agreed that if an asymptomatic person has abnormally high levels of arsenic in the urine, the absence of symptom's cannot be interpreted as an indication of a minimal exposure. 114/

On the presence of levels of arsenic in the 269 cases reported to Blodgett, the data showed the following:

URINE ARSENIC LEVELS 115/

LEVEL (mcg/L)	#	%	Cumulative %
>100,000	3	1.1	1.1
>50,000	3	1.1	2.2
>25,000	7	2.6	4.8
>10,000	10	3.7	8.5
>2,000	33	12.3	20.8
>200	43	16.0	36.8
>10	61	22.7	59.5
<10	99	36.8	
Unknown	10	3.7	
TOTAL	269	100.0	

Thus, if urine levels of over 200 mcg/L or more are taken into account, and the five intentional exposures are eliminated, 94 cases

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114/ EPA Ex. 7 (p. 16). See also, Dr. Hall's testimony EPA Ex. 117 (p. 31), and Dr. Aranow's testimony, EPA Ex. 184 (pp. 6, 8). Dr. Hall stated that, "The purpose of measuring urinary arsenic levels is to determine if there is an excessive arsenic excretion, currently thought to be the most accurate quantifiable predictor of an excessive body burden of arsenic and thus predictive of the potential for the development of a significantly symptomatic poisoning." Dr. Aranow considered that a level of 50 mcg/L, presumably in a 24-hour collection, was an indication of an excessive body burden.

115/ EPA Ex. 203. As noted, these results are from spot urine tests. The figures in 203 include 5 intentional exposures; No. 2 (198,450 mcg/L), No. 45 (34,700 mcg/L, No. 1 (9,360 mcg/L), No. 248 (3,715 mcg/L), and No. 25 (2,020 mcg/L). EPA Ex. 201.

(34.9%) represent the population put at risk. This number of incidents cannot be dismissed as insignificant or of only minimal concern. 116/

Where abnormal levels of arsenic are detected in the urine, Blodgett's general measures for decontamination include the induction of vomiting with syrup of ipecac or treatment by lavage (washing out the stomach with fluids). In addition, chelation with BAL (Dimecaprol) is instituted followed by oral treatment with D-penicillamine, another chelating agent, to help eliminate the arsenic from the body. BAL administration requires painful intramuscular injections. Chelation is also accompanied by side effects such as nausea, diarrhea, and vomiting as well as pain and sterile abscesses at the injection site, mild shock, hopotension, tachycardia, anorexia, convulsions and restlessness. 117/

Not all poison control centers agree on how asymptomatic patients should be treated for arsenic exposure. 118/

For example, one simply recommends dilution and observation for symptoms, unless the patient ingested more than 5 ml of Terro (about one-sixth of a bottle). If more than 5 ml of Terro have been ingested or if symptoms such as vomiting or diarrhea occur, the patient is treated with

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116/ The three cases with urine levels over 100,000 mcg/L (case Nos. 2, 77 and 22) were all cases in which symptoms were manifested. Two involved exposures of children under six years, one (case No. 77) to a milkcup and one (case No. 22) to a bottle. In both cases Terro was the product. In one case (No. 77) vomiting was the only symptom. Of the remaining 96 cases, 86 involved accidental exposure to children under six, the great majority being accidental exposures to a bait station. EPA Ex. 201.

117/ EPA Ex. 7 (pp. 19-20); EPA Ex. 192 (p. 17); EPA Ex. 117 (pp. 38-40).

118/ See EPA Ex. 91; Tr. 261.

syrup of ipecac to induce vomiting and observation. 119/ Another will also recommend dilution and observation unless an ingestion of greater than 2.5 ml or an unknown amount is ingested from the bottle, in which case vomiting is induced with possible referral to a health care facility. 120/

Dr. Litovitz, Director of the National Capital Poison Center, recommends that even patients who ingest just a "lick" of an arsenical ant bait should undergo gastic decontamination by administering syrup of ipecac and urine assay for arsenic. More specifically, Dr. Litovitz believes that spot urine determinations should be obtained for all pediatric arsenic ingestions of 100 mg of sodium arsenate (3.6 ml of Terro or 5.7 ml of Jones), but treatment should not wait for laboratory results if it takes a day or more to obtain them. In that case, BAL chelation therapy should be administered to all patients with symptoms of arsenic poisoning or with a history of ingestion of 200 mg of sodium arsenate or more. Also asymptomatic patients with elevations of urine (100 to 2000 mcg/L) discovered more than one day after exposure due to laboratory delays may be treated with oral chelation with penicillamine. 121/

At the Poison Control Center at Children's Hospital in Detroit, Michigan, all probable ingestions of sodium arsenate by children are

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119/ Minnesota Regional Poison Center and St. Paul-Ramsey Medical Center, Senoret Ex. 69 (p. 2).

120/ University of Wisconsin Hospital Regional Poison Center, Senoret Ex. 1 (p. 1).

121/ EPA Ex. 7 (p. 21-22). 200 mg. of Terro is the equivalent of about 1/4 of a 1 ounce bottle, and of somewhat less than 1/2 a 1 ounce bottle of Jones. Supra, p. 23.

referred for medical evaluation, decontamination of the stomach, usually by lavage, followed by the administration of activated charcoal and collection of a 24-hour urine for arsenic concentration. If any symptoms develop or the exposure could have exceeded 1 mg of elemental water soluble arsenic per kilogram of body weight, 2 or more doses of activated charcoal are advised and the administration of BAL therapy. If the urine arsenic is 50 mcg/L or greater (presumably on a 24-hour collection) in an asymptomatic patient, a three-day course in D-penicillamine is recommended on an out patient basis. 122/

Elevated urine arsenic levels have been shown even after what would appear to be a low dose exposure to a bait station. Children exposed to a cardboard bait station displayed urine levels as high as 24,500 mcg/L in spot urine tests. 123/ Measured over a 24-hour collection the value could be higher or it could be lower. 124/ It must also be recognized that the urinalysis discloses only the presence of arsenic in

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122/ EPA Ex. 184 (pp. 7-8).

123/ See Dr. Litovitz's testimony, EPA Ex. 7 (p. 21). See also case No. 107 in the Blodgett study. For point of reference, a 1 ml Terro bait station would contain 28 mg of arsenic. Supra, p. 25, n. 78. This would be the equivalent of 28,000 mcg. See Tr. 2303.

124/ A 24-hour specimen would average out variations in the clearance of arsenic from the blood by the kidneys and variations in the concentration of and volume of urine produced. EPA Ex. 117 (p. 31). See also Tr. 856, 2334. Such variations presumably explain why a 22 month-old child with only 28 mcg/L arsenic in urine on a spot sample still exhibited symptoms of vomiting and diarrhea. See EPA Ex. 200 (case No. 62). Most of the Blodgett samples are taken 2-4 hours after exposure, but some could be taken 8-10 hours after exposure. Tr. 1106.

the urine and arsenic ingested from sources such as food would be included. 125/ It is the opinion of the EPA's expert witnesses, however, that dietary factors and other sources would not account for arsenic levels of 200 mcg/L or more in urine, especially in children under six. 126/

Finally, the EPA's expert witnesses believed that the prompt treatment by inducing vomiting and administering chelating therapy in persons with high urinary levels of arsenic is instrumental in preventing the development of symptoms or at least decreasing the morbidity associated with the poisoning incidence. 127/

Dr. McCoy summed up the reasons for Blodgett's protocol as follows:

> Well, there are basically two approaches, a very general approach that says that if you interrupt a toxin before it exerts its effect, then you're much more likely to prevent the effect. So that general approach is true not just in the case of arsenical exposures or sodium arsenate exposures, but it's true in any toxic exposure or potentially toxic exposure.
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> We're basically talking a risk benefit type of situation and a judgment. And to the addition of the chelators or any of the other treatment regimes that are advised, or at least we advise, in the exposure address the toxic effects, potential toxic effects in two ways.

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125 See Tr. 2331; EPA Ex. 117 (pp. 24-29).

126/ See Tr. 1110; EPA Ex. 184 (p. 7); EPA Ex. 7 (pp. 15-16). EPA Ex. 139. According to Dr. Litovitz, the large number of cases in the Blodgett series of children under 5 years with urine levels below the lower limit of detection of the assay (10 mcg/L) leads to the conclusion that unexposed children have only trace amounts of arsenic in their blood or urine. EPA Ex. 7 (pp. 15-16). Dr. Banner criticizes the Blodgett study because the spot urinalysis does not disclose what amount of arsenic in the urine came from other sources. Senoret Ex. 12 (p. 3). The weight of the evidence, however, supports Dr. Litovitz's opinion.

127/ EPA Ex. 7 (pp. 19, 22); EPA Ex. 192 (pp. 11-12); Tr. 1093-94.

> One, there may be toxic effects that are strictly attributable to the sodium arsenate itself. There may be changes of sodium arsenate to sodium arsenite over time.
>
> We know that, although sodium arsenate is rapidly excreted and there's a considerable amount immediately following the exposure, in the first few hours or 24 hours in exposures that are quite significant, we see that that level is maintained or the urinary excretion, although it falls off, it's still very high a number of days later.
>
> The longer, as is pointed out in a number of the articles, a compound is in the body, the greater the probability for toxicity. If there is a toxic effect to sodium arsenate or if there is any conversion to sodium arsenite, the rationale, we feel, is reasonable to put a chelator in there that will take care of anything that is converted or that will enhance the excretion of the sodium arsenate. Then it makes sense. And so, for those reasons, that's why we approach the treatment the way we do. 128/

Not all poison control centers view levels of arsenic in the urine as necessarily indicators of a poisoning. Instead they rely on the presence of symptoms. This was made clear by Senoret's experts.

Thus, Dr. Samuel Hall, who is a toxicologist and head of the Section of Clinical Toxicology and Drug Abuse of the St. Paul Ramsey Medical Center and Medical Director of the Minnesota Regional Poison Center, testified that where there are few, if any, signs and symptoms of toxicity following an exposure to Terro, the prescribed treatment is dilution with fluids and observation. If symptoms of toxicity occur including vomiting or diarrhea or the patient ingests more than 5 ml of Terro, the patient is treated with syrup of ipecac and observation, with possible

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128/ Tr. 1093-94.

referral to a health care facility. Any patient with more severe symptoms is referred to a health care facility. 129/

Dr. Hall and Dr. Richard Kingston, supported in part by a grant from Senoret, made a study of all cases of exposure to Terro reported to the Minnesota Regional Poison Control Center ("MRPCC") over a 4 1/2 month period from March 1, 1988 through July 16, 1988. The purpose of the study was to determine if more "aggressive" intervention in cases of exposure to Terro is warranted than is provided in the treatment protocol. 130/

The results reported were as follows: 149 cases of exposure were reported, 95% of which (142) involved children under six years of age. The source of exposure was the bait station in 136 (915%) of the cases, and the remaining were directly from the bottle. All but one involved an accidental exposure.

Three of the cases of accidental exposure were symptomatic within the first hour of ingestion. An additional patient was treated with syrup of ipecac and was noted to have loose stools in the next 12 hours.

Four of the 149 patients were treated with syrup of ipecac. The remaining 145 patients required only dilution with milk or water and observation.

Post exposure follow up of one week to three months was accomplished in 125 patients (84%). No patient reached in the post exposure follow up

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129/ Senoret Ex. 69 (p. 2); see also Senoret Ex. 72 (p. 5). An exposure of 5 ml of Terro is equivalent to a teaspoonful, EPA Ex. 7 (p. 5).

130/ Senoret Ex. 74.

had experienced any complication secondary to the ingestion or sought additional medical treatment and all were in their normal state of health as determined by patient or guardian. It was concluded that no reason appeared to change the Centers treatment protocol. 131/

The EPA critizes the Senoret study because it does not contain any information about the levels of arsenic in the urine. 132/ Given the large number of exposures reported to AAPCC over the 4 1/2 month period (149 cases compared to 72 reported to Blodgett during the comparable period) it would be unusual to assume that none of the cases reported to AAPCC had arsenic levels over 200 mcg/kg. If, in fact, no excess urine levels were shown this would lend support to Senoret's argument that some of the arsenic could have come from sources other than Terro. Consequently, the study does give some information about the arsenic exposures. As already noted, the record discloses that clinical manifestations of arsenic poisoning appear within 12 hours. 133/ If this is true, then the study would tend to rebut the position of EPA's experts that more aggressive therapy such as chelation prevented the manifestation of acute toxicity symptoms. It is less persuasive in rebutting the position of the EPA's experts with respect to forestalling delayed symptoms. The study would be more persuasive of the lack of injury in these sodium arsenate ant bait exposures if arsenic levels in the urine had been measured at the time of followup and no abnormally high levels had been shown.

131/ Senoret Ex. 74 (pp. 4-5).

132/ EPA's Reply Br. at 21.

133/ See supra, p. 41, n. 120.

4. Risk From the Bottle

As already noted, the greatest percentage of exposures have been to the bait station, which apparently is often not placed in areas inaccessible to children, notwithstanding the directions on the label. The EPA claims, however, that there is also a risk from the bottle. 134/ Underlying the EPA's objection is the claim that the cap is easily removed or the bottle is frequently left open. 135/

Since January 1988, Senoret has voluntarily been selling Terro in a bottle with a child-resistant cap. 136/ It is only proper, then, that the risk be assessed on the basis of the bottle being packaged with a child-resistant cap.

Dr. Litovitz expressed concern that children could get into the contents of the bottle notwithstanding its child-resistant packaging, because such caps are ineffective with sticky liquids. 137/ This concern arises from her study of accidental ingestions of oral prescription drugs which disclosed that the functioning of continuous threaded closures was

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134/ EPA Intial Br. at 51-52; Reply Br. at 38.

135/ Id. It should be noted that the fatality with Terro in the record involving a 5 year old child who died after drinking from a bottle apparently happened because the children had punched a hole in the bottle top with a hammer and nail. EPA Ex. 9. This seems to have plainly been an isolated occurrence, and does not indicate that there is a risk of the cap being easily removed or the bottle being frequently left open, which seems to be the grounds underlying the EPA's objection.

136/ Senoret Ex. 30 (p. 4); Tr. 1713. No finding is made as to whether the child-resistant cap meets EPA standards as claimed by Senoret, Br. at 58-59, Reply Br. at 40-41, or does not meet the standards as implied by Mr. Blondell, EPA Rebuttal Ex. 1 (pp. 7-8), because the evidence is insufficient to make that determination.

137/ Tr. 1287. See also Dr. Alan Hall's testimony at Tr. 784-785.

affected by sticky liquids. 138/ This is undoubtedly the case in Terro as well. 139/ It does not in itself, however, provide a basis for finding that this defect has made the Terro bottle a risk of any consequence. For one thing, we need to know more about where Terro is stored when it is not in use. 140/

The Blodgett data is again instructive in determining how great the risk from the bottle.

The Blodgett data covers 73 cases during the 7 1/2 month period from January 1, 1988 through August 16, 1988. 141/ Nine cases, (12.3%) of exposure to the bottle by children under 6 are included. In two of these cases the levels of arsenic were so high as to indicate that the child may have drank from the bottle although no symptoms were reported. 142/ In two other cases, the urine levels were more than 200 mcg/L. 143/

138/ EPA Rebuttal Ex. 1 (p. 7), EPA Ex. 6A. Dr. Litovitz reported one case of moderate poisoning where the child drank from the bottle. She reports that the child opened the bottle himself but does not disclose whether it contained a child-proof cap. EPA Ex. 7 (pp. 12-14); Tr. 1242-46. Since the incident occurred in July 1987, the likelihood is that it did not.

139/ See EPA Exs. 76-84; Senoret Exs. 33-38; Tr. 1707-10.

140/ See EPA Ex. 6A (p. 9).

141/ EPA Ex. 8. The cases are case No. 184 (apparently listed out of order) and case Nos. 198-269.

142/ See EPA Ex. 8, case No. 204, where the urine level was 14,250 mcg/L and case No. 240, where the urine level was 27,480 mcg/L.

143/ See case Nos. 208 (4400 mcg/L) and 232 (440 mcg/L).

Children in the other five cases neither had high urine levels nor did they exhibit any symptoms. 144/

It is assumed that all nine cases involved child-proof bottles. In only two, however, did it appear that the child may have drank from the bottle. In the other cases, the indication is that if the bottle is at risk it is because of the child coming into contact with the outside of the bottle and in the majority of these cases there is no evidence of poisoning at all.

I find, acordingly, that the risk of drinking from the bottle itself is not a widespread risk arising from the way that the product is used. There is, however, a risk of coming into contact with sodium arsenate on the outside of the bottle which in itself probably does not occur very often but is a risk to be considered along with the risk of the ant bait.

B. The Risk of Sodium Arsenate Ant Bait Products

In evaluating the risk, we have first of all to consider the evidence of acute poisonings that have occurred through the use of these sodium arsenate ant bait products. According to the AAPCC for 1987, eight children under six suffered exposures which were diagnosed as having more than a minor effect. 145/ The AAPCC data, however, does not tell the entire story. Dr. Litovitz estimated that the amount of exposures reported to the AAPCC were roughly 1/4 of the total exposure. 146/ A possible 30

144/ See EPA Ex. 8, case Nos. 209, 214, 245, 247 and 259.

145/ EPA Ex. 133 (Table I-21B).

146/ EPA Ex. 7 (p. 9).

definite cases of arsenic poisoning a year are obviously of concern and in themselves justify an examination into the benefit's of the products. 147/

The EPA, further, does not rely simply on the symptomatic cases to establish the risk. Aside from the immediate acute symptoms of sodium arsenate poisoning, there are also the risks of the delayed effects of arsenic poisoning, if the arsenic remains in the body, such as kidney failure, liver injury, anemia, and injury to peripheral nerves (peripheral neuropathy). 148/

The EPA argues that any consideration of the comparative toxicology of sodium arsenate (pentavalent arsenic) and sodium arsenite (trivalent arsenic) is irrelevant. 149/ I disagree. Inherent in the assessment of the risk by the EPA's experts is the greater toxicity of trivalent arsenic

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147/ The EPA argues that any adverse effect is sufficient to justify cancellation unless it is outweighed by the benefits. Initial Br. at 6-7. It ignores the language in FIFRA, however, that the risk must result from the use of the product in accordance with widespread and commonly recognized practice. Evidence showing that in a few instances the pesticide was intentionally misused or negligently applied would not demonstrate a risk resulting from the use of the product in accordance with widespread and commonly recognized practice. Cf, Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 641 (1980) (Occupational Safety and Health Act of 1970, does not mandate a risk-free workplace). That, however, is not the situation shown to be present here.

148/ EPA Ex. 7 (pp. 14-15); EPA Ex. 117 (p. 19). The EPA also claims that arsenic can create brain damage, and is a well-recognized human carcinogen. Initial Br. at 22-23. These effects, however, appear to have resulted from chronic exposure over a period of time. There is no evidence that the use of these ant baits give rise to a risk of chronic exposure. I also agree with Senoret that this record is inconclusive on whether an acute exposure to any of these sodium arsenate ant bait products can have teratogenic or mutagenic effects. Intial Br. at 4-7.

149/ Reply Br. at 46-47.

and the fact that some percentage of sodium arsenate is metabolized into sodium arsenite in the human body thus making even small dosages of sodium arsenate hazardous. 150/

In short, the assessment of risk in this case is the evaluation of the toxicity of sodium arsenate itself. Well qualified experts have testified on both sides of this question. The EPA experts believe that the risk is great enough to justify the administration of unpleasant and potentially toxic measures such as chelation therapy. Senoret's experts disagree. In all instances, the treating physician is, in effect, doing a risk-benefit analysis based on the present uncertain knowledge about sodium arsenate, namely, whether the risk of toxic effects is sufficiently great to justify the therapy prescribed. As Dr. Banner described it, there is a professional conflict of opinion on the issue. 151/

It is not the purpose of this proceeding to resolve this conflict of medical opinion. The purpose, instead, is to determine whether the record supports a finding that the risk of these sodium arsenate ant bait products justifies cancellation by the EPA, unless their benefits outweigh the risk. On both of these issues, the EPA has the burden of going forward to present an affirmative case for the cancellation, but

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150/ See e.g., Dr. Litovitz's testimony, EPA Ex. 7 (p. 14); Dr. Alan Hall's testimony, EPA Ex. 117 (p. 17) and Tr. 796.

151/ Tr. 1613. See also Dr. McCoy's statement, supra, p. 43; Dr. Samuel Hall's testimony, Tr. 1927-29. A cost-benefit analysis also underlies the conclusion reached in the Kingston and Hall study. See Senoret Ex. 74 (pp. 8-9).

the ultimate burden of persuasion rests with petitioners. 152/ This regulation has ample authority in the law. 153/

Drs. McCoy, Hutton, Litovitz and Aronow, who are all emminently qualified experts, testified as to the risk of these products on the basis of their study of the literature and their own experience. Exposure data in the record shows that there is a risk that individuals and particularly small children will be exposed to these products. While in the majority of cases there is no poisoning, there are enough instances where either overt symptoms have been shown, or where the presence of arsenic in the body of the exposed person creates a concern that there may be toxic effects unless prompt treatment is given. 154/ Finally, there is the lethality data indicating that sodium arsenate can have toxic effects even at small doses. This evidence more than adds up to a prima facie case. Under these circumstances it is not enough that experts may disagree on the hazards of being exposed to these sodium arsenate ant bait

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152/ 40 C.F.R. § 164.80(a) and (b).

153/ Industrial Union Dept. v. American Petroleum Institute, 448 U.S. 607, 653, n. 61 (1980; Environmental Defense Fund v. Environmental Protection Agency [Velsicol Chemical Co.], 548 F.2d 998, 1004, 1012-1018 (D.C. Cir. 1976), cert. denied, 431 U.S. 925 (1977); Environmental Defense Fund v. Environmental Protection Agency [Shell Chemical Co.], 510 F.2d 1292, 1297, 1302 (D.C. Cir. 1973).

154/ In addition to the AAPCC data discussed above, other human experience data mentioned by Mr. Blondell (EPA Ex. 1 (pp. 36-50)), confirms the widespread exposure to these ant bait products. In one instance, ingestion from a bottle appeared to have been fatal to a 5 year old child. EPA Ex. 1 (p. 38). One incident mentioned by Mr. Blondell as a serious incident in the EPA's Pesticide Incident Monitoring System ("PIMS") was said by him to involve the ingestion by a three-year-old, 36 pound girl who reportedly ingested 2 teaspoons of Terro from an ant trap device placed in a lamp stand. EPA Ex. 1 (p. 38). The PIMS report relied on, however, does not support this statement other than that there was exposure to a sodium arsenate ant killer liquid ingested from an ant trap device. EPA Ex. 9, Tr. 229.

products. Senoret's burden is to show that the preponderance of the evidence favors its position that the exposures to sodium arsenate ant baits are only of minimal concern. I find that the record does not support any such conclusion. Indeed, so far as the treatment of sodium arsenate exposures is a reflection of the risk from them, notwithstanding the opinion of Senoret's experts, one is left with the definite impression that the "aggressive" treatment of exposures is wholly justifiable given the present uncertain knowledge about the lack of toxicity of sodium arsenate.

The accidental exposures to these sodium arsenate ant bait products, involving as they do a large number of children under six, apparently happen because users simply are unable to keep them out of the reach of small children. How great is this risk, of course, is a matter of judgment. It is found here that the AAPCC data showing that the accidental exposure cases in 1987 resulted in 140 cases where some symptoms were shown plus the Blodgett data showing that about 33% of the 269 cases reported to Blodgett during the 43-month period involved children under 6 years of age who either had symptoms or unusually high levels of arsenic in the urine or both, demonstrates that a sufficient number of persons are put at risk not only of the adverse effects of arsenic poisoning, but also of the discomfort and side effects associated with the treatment for arsenic poisoning to warrant cancellation of these sodium arsenate ant bait products unless the benefits of having them available exceed the risks. 155/

155/ Fatsco and Protexall appear to be at least as potentially toxic as Terro. While Jones is sold in a lower concentration of sodium arsenate, it appears to be still toxic enough to be included in the ban. The EPA's

(Footnote continued)

IV. The Benefits of Sodium Arsenate Ant Bait Products

A. The Efficacy of Sodium Arsenate Ant Baits

The EPA argues that contrary to what was stated in the notice of intent to cancel, the record established that sodium arsenate ant baits are not the most effective ant bait products for the control of sweet-eating ants. In fact, relying on the testimony of Mr. Brassard who discounted all evidence tending to establish the effectiveness of the sodium arsenate ant baits, the EPA argues that there is no valid proof that sodium arsenate is effective at all under actual use conditions. 156/

Dr. James F.A. Traniello an expert in entomology and one who has done considerable research on the behavior, communication and foregoing habits of ants, testified on behalf of Senoret. 157/

Dr. Traniello testified that in his opinion delayed action toxicants are preferable for use in the home for the control and management of ant

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(Footnote 155 cont'd)

experts apparently considered Jones as hazardous as the other sodium arsenate ant bait products. Jones points to what it claims are the small number of exposures with minor or moderate effect reported to AAPCC in 1987. Jones' Post-Hearing Br. at 3. Yet it is to be noted first, that Jones is the only other sodium arsenate ant killer besides Terro to be reported as resulting in a minor or moderate effect, and second, that of the 14 ant killer cases reported as having a moderate effect, three involved Jones. EPA Ex. 33 (Table I-25B). The smaller number of cases involving Jones as compared to Terro may well be explained by the fact that Terro is by far the largest seller of these sodium arsenate ant killers. Compare Terro's sales in 1987 (Senoret Ex. 40) with the total sales of 1.2 million bottles calculated by Mr. Dumas. EPA Ex. 214 (p. 7).

156/ EPA Initial Br. at 98-109; Reply Br. at 85-96. See 53 Fed. Reg. 24791 (June 30, 1988) for EPA's statement in the notice of cancellation that sodium arsenate ant baits "are considered the most effective ant bait products for the control of sweet-eating ants."

157/ Senoret Ex. 86 and supplement to that statement. The EPA waived crossexamination of Dr. Traniello. Tr. 2717.

infestations. The very nature and structure of an ant colony lends itself to the use of a toxicant in a bait which can be brought back to the nest and fed to other members of the colony. Additionally, a generally accepted food (such as sucrose) used in the formulation of the bait has the broadest applicability.

Dr. Traniello explained that the ants most likely to be seen in the home are foraging ants who leave the nest in search of food, which they then bring back and share with the colony including the queen and brood. They do this by taking the food in their crop and then regurgitate the food to the other ants in the colony. Since less than 25% of the worker population of a colony at any one time are foragers, a control procedure involving spraying ants which are visible with a fast-acting toxicant would destroy only a small proportion of ants, and means only that other foragers would replace them. Given this pattern, then, effective control of the ants in the home can be achieved with a product having a temporarily delayed effect resulting from a toxicant carried to the nest and distributed to the entire colony. Using a delayed action toxicant in a bait also involves a small amount of effort and expense.

Dr. Traniello was also of the opinion that since many species of ants use carbohydrate foods, a sucrose bait should be widely-accepted and the high concentration of sucrose should make the bait highly profitable in comparison to other available food sources.

Dr. Traniello further stated that under conditions of strong food recruitment stimulated by the concentrated sucrose solution, the delivery rate of the toxicant to the nest is very high. Studies have shown that within 30 hours, a food will be distributed to all workers. Depending on

a number of factors, foraging ants can carry away one milliliter or more of a toxicant containing bait from within a few days, a few hours, or a shorter period of time. The ant's speed of removal of the toxicant depends on the crop size, the size of the colony, the nutritional demands of the colony and the proximity of the food source to the nest. 158/

Dr. Traniello's statements as to the desirability of a delayed action toxicant for use by the homeowner are not really contested. The EPA's position, rather, is that Terro and the other sodium arsenate ant bait products are not effective because it has not been demonstrated that sodium arsenate is a delayed action toxicant.

Dr. Traniello did a preliminary test to determine whether there was indication that Terro was a delayed action toxicant. Workers from queenright laboratory colonies of the black carpenter ant (Camponotus pennsylvania), the pyramid ant (Conomyrma sp.) and the velvety tree ant (Liometopum opiculatim) were used. Fifty workers of the pyramid ant and the velvety tree ant were used (these ants are classified as "Dolichoderinae"), and twenty workers of the capenter ant were used (this species is classified as ("Farmicinae"). Subcolonies were established, one for treatment with Terro and one for control. Twenty-percent of the workers in each of the experimental subcolonies were marked with a small dot of white paint, allowed to take a single crop load of Terro and then returned to the subcolony of origin. Twenty-percent of the workers in the control colonies were similarly removed, marked with paint and returned to their respective colonies.

The results were as follows:

158/ Senoret Ex. 86; Senoret's proposed findings Nos. 103-105 inclusive.

First, there was no mortality in any subcolony six hours past treatment.

Second, in the two Dolichoderinae species the following results were shown:

Velvety tree ant - In the treated colony, 12% of the ants (all marked showing that they had fed off the bait) were dead after 24 hours and 32% of the ants were dead after 72 hours (6 were marked ants and 10 were unmarked ants), compared to none of the ants dying in the control nest either at 24 hours or 72 hours.

Pyramid ant - In the treated colony, 22% of the ants were dead after 24 hours (4 marked and 7 unmarked), and 70% were dead after 72 hours (7 marked and 28 unmarked), compared to the control where only 4% (all unmarked) died after 24 hours and only 6% (all unmarked) died after 72 hours.

As to the carpenter ant (Formicinae species), in the treated colony none died after 24 hours, 15% were dead after 72 hours (2 marked and 1 unmarked), and 50% were dead after 1 week (4 marked and 6 unmarked), compared to the control where none was found dead.

Additional tests were also run. In one test, fifty velvety tree ants were allowed to feed at a 0.1 ml drop of Terro. Fed workers were marked with a drop of paint. A total of 15 crop loads by 10 foragers were allowed to be delivered to the subnest. What seems to be most significant about this test is that the brood (larvae) were placed in both the experimental and the control nests. At 72 hours the brood weight in the treated group had dropped from 12.3 mg to 6.7 mg while in the control group the brood weight only dropped from 15.8 mg to 15.0 mg.

In another test, black carpenter ants were allowed to feed at 0.1 ml droplet of Terro and return to the nest where the queen was. Five workers and the queen were dead after 12 days.

Finally, Dr. Traniello observed that frequent oral exchange of food (trophallaxis) was occurring in the treated colonies following the return of fed individuals, suggesting that the bait was distributed to subcolony members. 159/

Mr. Brassard was extremely critical of Dr. Traniello's studies, believing they were too flawed to be of any value in judging product efficacy. 160/ Mr. Brassard seemed objective enough in his analysis of efficacy studies relating to other products, but this cannot be said of his opinions with respect to the efficacy of sodium arsenate. As to sodium arsenate, he appeared to be more of an advocate for the EPA's position on its asserted inefficacy than an impartial examiner of this ant bait product.

An example is Mr. Brassard's analysis of an efficacy study on the TAT-I bendiocarb bait station, Reg. No. 506-143. 161/ Mr. Brassard called the bendiocarb study a well-designed outdoor field test, which provided useful information about the TAT-I ant trap. 162/ When one examines the condition of the test, however, several things are to

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159/ Senoret Ex. 90.

160/ Supplement to EPA Ex. 119 at 4. Mr. Wagner was also critical of Dr. Traniello's test because it was done only on the concentration of sodium arsenate in Terro. Tr. 2921. The test was still relevant, however, to the efficacy of Terro, whether or not it was relevant to other concentrations of sodium arsenate.

161/ EPA Ex. 284 (also Senoret Ex. 109).

162/ EPA Ex. 119 (p. 46).

be noted. First, the trap was placed 1 to 2 inches from the nest outdoors. 163/ Evidence also disclosed that there was a drought at the time and the ants may have been under food stress (a fact brought out on crossexamination). 164/ Mr. Brassard was willing to assume that the test showed bait transfer. He admitted, however, that there was not enough information to really determine this. 165/ The fact that there were significantly more larvae in the control groups than in the treated groups was an inconsistency that did not bother him. 166/ Nevertheless, it could have a bearing on how representative the treated groups were for purposes of drawing conclusions about colony elimination.

Mr. Brassard sums up this study as demonstrating colony elimination when the ants are under food stress and not as representative of a situation where somebody placed bait stations in the house. 167/

163/ EPA Ex. 284 (p. 6)

164/ Tr. 3306-3308, 3571-3572.

165/ Tr. 3311-3312, 3575

166/ See Tr. 3302. Two colonies were used as control for both the original test and an ultra violet test that was also run. Tr. 3292. The test itself did not actually show whether any dead larvae were found in the treated nests. Brassard found out there were by a telephone call to one of the researchers after he had completed his written testimony. Tr. 3292-3294, Senoret cross-examine Ex. 41.

167/ Tr. 3524. The EPA has not really answered Senoret's arguments (Senoret Br. at 87-88) about the deficiencies of EPA Ex. 284. See EPA Reply Br. at 81-82. The reference to Mr. Brassard's testimony is to his analysis of EPA Ex. 282, an efficacy test done on the 0.05% FICAM (bendiocarb) formulation. See Tr. 3567-3569. The product studied in EPA Ex. 284, has 0.03125% active ingredient.

To sum up, if the TAT-I test even with the limitations described by Mr. Brassard apparently demonstrated to him that the product will perform as well as, if not better than Terro in the house, one is left with the question why Dr. Traniello's tests, which seemed well designed to test bait transfer and delayed toxicity in the laboratory, admittedly desirable qualities to control ants in the house, are nevertheless found by Mr. Brassard to not support Dr. Traniello's tentative conclusion that his studies suggest that Terro may have these qualities. 168/

There is other evidence in the record which Mr. Brassard is all to ready to discount but which does support Senoret's position that sodium arsenate ant bait are effective for controlling small infestations of sweet-eating ants in the home.

Thus, there is the opinion rendered by Dr. Douglas Sutherland, an EPA entomologist, to the EPA's Special Review Manager in connection with the cancellation of sodium arsenate ant baits. 169/ In this opinion, Dr. Sutherland stated that "sodium arsenate is viewed by experts as the most efficacious compound for controlling sweet-eating ants. 170/

168/ Mr. Brassard admitted that none of the field efficacy studies demonstrated bait transfer, and that a well designed laboratory study would be an acceptable way to demonstrate this. Tr. 3084, 3441. Although Mr. Brassard professed to have some problems with the design of Dr. Traniello's study (Supplement to his direct testimony and Tr. 3426), Dr. Traniello appears to have satisfactorily answered these in his supplemental statement. Supplement to Senoret Ex. 86.

169/ Tr. 3348-3351; Senoret Cross-Examination Ex. 42.

170/ Senoret Cross-examination Ex. 42. Virtually the same opinion was also stated in the EPA's notice of cancellation. 53 Fed. Reg. 24791 (June 30, 1988).

Mr. Brassard testified that he talked with Dr. Sutherland who told him that he had done a very brief review and did not have much time to spend on the questions. 171/ Nevertheless, I am unwilling to assume that Dr. Sutherland did not conduct a responsible review. This does not mean that the EPA is bound by Dr. Sutherland's statement that sodium arsenate is the most efficacious compound, anymore than it is bound by a similar statement in the notice of cancellation. 172/ What it does mean is that it is difficult to believe that Dr. Sutherland would have rendered such an opinion, if, in fact, he did not believe that there was firm evidence showing that sodium arsenate was an effective means for controlling sweet-eating ants. 173/

Evidence of the effectiveness of sodium arsenate ant baits is also found in the United Stated Department of Agriculture's assessment of inorganic arsenicals in 1980. There it is stated that "sodium arsenate is an effective toxicant against most species of common ants. Satisfactory

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171/ Tr. 3399-3402, 3623-3624.

172/ See supra, p. 60, n. 170.

173/ For what Dr. Sutherland did consider we are forced to rely on Mr. Brassard's conversatons with him. Mr. Brassard stated that Dr. Sutherland told him that he talked to Bob Wagner (who also testified in this proceeding), another person who was an extension agent, checked some general references, the USDA assessment on sodium arsenate (EPA Ex. 286), a study of Ebeling on Urban Entomology (EPA Ex. 218), the study by Eichler & Kleinsorge (EPA Ex. 243) and looked at several letters submitted by Mr. Roberts, President of Senoret (EPA Ex. 271). Tr. 3624. The EPA argues that they do not show that sodium arsenate is the most effective ant bait. Reply Br. at 88. Accepting this as true, they appeared to contain sufficient evidence of sodium arsenate's efficacy to enable Dr. Sutherland to reach that conclusion.

control can be expected when small populations are present or when there are alternative sources of food outside the area of annoyance." 174/

Finally, the efficacy of sodium arsenate ant baits is demonstrated by the consumer acceptance of these products. 175/ Apparently, since 1980, as Mr. Brassard explained it, the Agency itself has recognized that that consumer acceptance in the market place is relevant in determining the efficacy of the product. 176/ The EPA argues that testimonials are merely the reflection of non experts who do not have the training and experience to make a judgement. 177/ Nevertheless, whether the ants have disappeared after the ant bait has been applied is a fact that would seem to be readily observable and to not require any special expertise. 178/ I would not, however, give the same weight to consumer acceptance as evidence that one product is in fact superior to another in performance. The

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174/ EPA Ex. 286. The assessment also stated that the advantages of sodium arsenate baits are 1) the transport of the toxicant to the nest for complete removal of an infestation, 2) low cost, 3) continuance of control, and 4) ease of use. The comparison with propoxur, as the EPA notes (Reply Br. at 87), may not be valid today, but that does not mean that sodium arsenate is still not an effective, low cost ant control for the consumer.

175/ See Senoret Exs. 33-65 for consumer letters attesting to the effectiveness of Terro in eliminating ants. In 1979, it was estimated that approximately 700,000 householders purchased containers of sodium arsenate. EPA Ex. 286 (p. 166). That number apparently has increased as much as 70%. See EPA Ex. 214 (p. 8).

176/ Tr. 3391, 3395-3396.

177/ EPA Reply Br. at 65, n. 34.

178/ The consumer letters put in by the EPA, EPA Cross-examination Exs. 22-34, do not demonstrate that Terro is ineffective, but only that it does not work against all ants or all infestations.

consumer is not an expert in comparative efficacy. In selecting one product over another, the consumer could well be influenced by factors other than those having to do with bait acceptance, bait transfer, and delayed action of a toxicant.

Accordingly, I find that sodium arsenate ant baits are effective ant bait products for the control of sweet-eating ants, especially when small populations are present. I do not find that they are the most effective of the ant bait products now on the market.

B. The Alternative Ant Bait Products

Among the alternative ant bait products identified by Mr. Brassard were the following formulations, listed by active ingredient ("AI"):179/

Arsenic Trioxide

Grants ant control, Reg. No. 1663-15
AI - 0.46% 180/

Bendiocarb

TAT-I ant trap, Reg. No. 506-143
AI - 0.03125% 181/

Borax

Terro California ant killer, Reg. No. 149-8
AI - 5.4%

Magi-kill jelly, Reg. No. 395-33
AI - 5.4%

179/ See EPA Ex. 119 (Table 3). See also EPA Ex. 214 (Table 1).

180/ Label is found in EPA Ex. 217. No efficacy data was offered.

181/ Label for the TAT-I ant trap is found in EPA Ex. 217. Efficacy data is found in EPA Ex. 284. See Tr. 3631. Bendiocarb is also known as FICAM. Tr. 3217

Black Leaf ant trap, Reg. No. 5887-134
AI - 5.4%

Pic ant trap, Reg. No. 3095-24
AI - 5.0% 182/

Boric Acid

Antrol ant killer formular II, Reg. No. 475-237
AI - 2.0%

Drax ant kill gel, Reg. No. 44313-6
AI - 5.0% 183/

Chloyprifos

Black Flag ant control system, Reg. No. 475-254
AI - 0.5% 184/

182/ Labels for Terro California ant killer is found in EPA Ex. 296; Tabels for Pic ant trap and Black Leaf ant trap are in EPA Ex. 217. The efficacy study for Magi-kill ant jelly is found in EPA Ex. 224; The EPA's product performance review for Terro California ant killer is found at EPA Ex. 281 (in camera). Tr. 3631.

On the effectiveness of Borax, it is instructive to look at the letter by the President of Senoret, Mr. Roberts to the EPA in January 1987. EPA Ex. 271. Mr. Roberts admits that Borax will work but takes three to seven days to kill ants. EPA Ex. 271 (p. 3). The implication is that sodium arsenate kills more quickly but Dr. Traniello's study is inconclusive on that point. See Senoret Ex. 90.

183/ Labels for both products are found in EPA Ex. 217. A label for Borax ant-kil gel is also found in EPA Ex. 296. The efficacy study for Drax ant kill gel is found at EPA Ex. 252.

184/ The label for Black Flag ant control system is found in EPA Ex. 217.

Hydramethylnon

Combat ant control system, Reg. No. 1730-68
AI - 0.9%

Combat ant control system II, Reg. No. 1730-73
AI - 0.9% 185/

Propoxur

Nott ant trap, Reg. No. 358-163
AI - 1.0%

Antrol ant trap, Reg. No. 475-173
AI - 2.0%

Black Flag ant trap, formula II, Reg. No. 475-213
AI - 0.25%

TAT ant trap, Reg. No. 506-137
AI - 0.25%

Grant's ant control, Reg. No. 1663-29
AI - 0.259%

Echols roach and ant killer, Reg. No. 3941-24
AI - 2.0% 186/

There were several other products named by Mr. Brassard as alternatives, but the discussion will be centered on the above products, because they appear to be better documented than the other alternatives and in

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185/ The labels for the Combat ant control system and Max force pharaoh ant killer are found in EPA Ex. 217. The label for the Combat ant control system II is found in EPA Ex. 288. The efficacy study for the Combat ant control system is found in EPA Ex. 277 (in camera), and the efficacy studies for the Max force pharaoh ant killer are found in EPA Exs. 238 and 248. Tr. 3632. The EPA's product performance review for this product is found at EPA Ex. 279.

186/ Labels for Black Flag ant trap; formula II and TAT ant trap are found in EPA Ex. 217. Labels for the other four products are found in EPA Ex. 296. An efficacy study the the TAT ant trap is found at EPA Ex. 282. The EPA's product performance review for this product is found at EPA Ex. 283. Propoxur is also known as Baygon. Tr. 3217.

themselves would be sufficient to establish the presence of available alternatives. 187/

Senoret has several objections to the above alternative formulations:

First, it points out that there are either no efficacy studies for the above formulations, or if there are any, they are inconclusive. 188/ Mr. Brassard's analysis of the efficacy studies, after taking into account the defects pointed out by Senoret, does show that while the efficacy studies may not conclusively demonstrate efficacy, they are sufficient to show that the product is not totally ineffective. 189/

187/ Excluded from Mr. Brassard's list are the ant bait formulations registered specifically for fire ants, namely, those with Avermectin B, as an active ingredient, and the hydramethylnon fire ant insecticides. There appears to be no claim in this proceeding that the sodium arsenate ant bait products will control fire ants. Further, these products are sold for outdoor use only. EPA Ex. 119 (p. 31). That does not mean that data on these products as potential alternatives is irrelevant in assessing the costs of cancellation, but only that a sufficient number of actual substitutes have been identified to make consideration of the fire ant products as potential alternatives unnecessary.

Also excluded from the list are the Max Force Pharaoh Ant Killer containing 0.9% hydramethylnon and the Pharorid ant growth regulator containing 10% methoprene. These are currently marketed only to Pest Control Operators (PCO's). EPA Ex. 117 (p. 24). Since there are a sufficient number of alternative products marketed to consumers, it is unnecessary to decide what additional costs are entailed if consumers could only turn to PCO's for alternatives. See Senoret's Initial Br. at 99-100.

188/ Senoret Initial Br. at 75-92; Reply Br. at 48-56.

189/ See Tr. 3377-3390. Dr. Traniello, however, was of the opinion that bait efficacy tests conducted by Robert Wagner with hydramethylnon in the Amdro formulation had positive results on several ant species. Senoret Ex. 88; EPA Ex. 304. The test was done with a soy bean oil bait. Mr. Wagner found the results to be more variable where other bait formulations were used, but considered hydramethylnon still to be a superior toxicant. EPA Ex. 225 (pp. 13-14).

That is the most that can be said about the efficacy studies of sodium arsenate.

Senoret also says that unlike Terro where the inert ingredients are known, the record is inadequate to evaluate the efficacy of alternatives because Senoret was deprived of the opportunity to cross-examine on the inert ingredients in the alternative formulations. The record establishes that in order to determine the efficacy of the product you must look at the inert ingredients as well as the toxicant and its concentration. 190/ The EPA refused to disclose the inert ingredients of the alternative formulations because this is confidential information under FIFRA § 10. 191/

The EPA's practice of using confidential information in its files and assuming that it is acceptable to take the word of EPA employees as to what that information shows, without revealing the information to the other side so as to permit the cross-exmination required for a full and true disclosure of the facts, has been a troublesome aspect of this

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190/ Tr. 2814-2815; 3591.

191/ FIFRA, § 10(b), 7 U.S.C. 136h(b), prohibits the Administrator from making public information containing or relating to trade secrets or commercial or financial information except that information relating to formulas of products may be revealed at a public hearing or in findings of fact issued by the Administrator.

Section 10(d)(17(c)), limits § 10(b) and does allow for the publication of certain data but does not authorize the disclosure of the identity or percentage quantity of any deliberately added inert ingredient.

proceeding. The fact that the information could be made subject to a protective order was not considered sufficient by EPA counsel. 192/

Let me at once say that I do not accept Mr. Brassard's statement of the inert ingredients as an adequate substitute for cross-examination. At the same time, neither am I prepared to assume that the manufacturer of these alternative formulations are adding inert ingredients that will make their products ineffective. The inert ingredients in the bait formation, emulsifier's, etc., are added to make the product effective. 193/ The most that can be said then about the absence of the disclosure of the identity of the inert ingredients is that it is another factor pointing to the inconclusive nature of the efficacy tests insofar as they

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192/ Tr. 3590-3604, 3656; see also infra, pp. 75-76. The EPA counsel, of course, were justifiably concerned about the penalties for unauthorized disclosure. See FIFRA, § 10(f), 7 U.S.C. 136 h(f). It was counsels' position that the information could not even be disclosed in camera without first obtaining the prior written consent of the registrants. This position is understandable because the Agency's rules of practice dealing with confidentiality of business information, 40 C.F.R. Part 2, Subpart B, do not address the disclosure of confidential information either publicly or in camera in an administrative proceeding except to parrot the words of the statute with respect to disclosure in a public hearing. See 40 C.F.R. § 2.307(g)(4). In view of the position EPA counsel has taken in this proceeding, the failure of the rules to deal with the matter should be remedied by the Agency or it risks having its proceedings delayed while permission is sought from the registrant and perhaps brought to a halt if the registrant does not agree to disclosure. Fortunately, that has not had to happen in this proceeding.

For the requirement that a party must be allowed to such cross-examination as may be required for a full and true disclosure of the facts, see 5 U.S.C. § 556(d).

193/ See e.g., EPA Ex. 289, where testing was done to determine the efficacy of a toxic food bait for the Argentine ant that would be competitive with the ant's natural food. Presumably, there is a mixture of active and inert ingredients which the manufacturer concludes gives optimum performance with that specific toxicant.

are being offered to show the superior efficacy of one product over another. Senoret's argument about being deprived of the right of cross-examination on the issue, so far as it relates to whether sodium arsenate is more effective than available alternatives, would be more persuasive if it had come forward with more positive efficacy tests as to sodium arsenate. In the case of Terro we do know the inert ingredient but there is still no efficacy data with respect to the Terro formulation to permit a determination as to whether Terro is any more effective than any of the alternative ant bait products. 194/

There is, of course, an assessment made by the United States Department of Agriculture in 1980, that sodium arsenate is more effective than propoxur (Baygon). 195/ We do not, however, have the basis on which that assessment was made, or the propoxur formulations against which the sodium arsenate was being compared. Weighing against that assessment is the efficacy study done in 1977 on the TAT ant trap which contained 0.25% propoxur as the active ingredient. The EPA's efficacy reviewer at the time questioned the claim that it destroys colonies "within 3-7" days. 196/ Nevertheless, the label claim that the bait destroys entire colonies of

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194/ For Senoret's contention that by not disclosing the inert ingredients, the EPA failed to establish that the alternatives are less toxic to ants than sodium arsenate, see Initial Br. at 93-94.

195/ EPA Ex. 286, and Senoret Ex. 93.

196/ EPA Exs. 282 and 283.

house ants appears to be currently accepted. 197/ It must, therefore, have been found that there was some support for this claim. It is also to be noted that no state cooperative extension has found sodium arsenate to be superior to other ant bait killers although some discuss the use of ant baits as a control. 198/

To sum up the efficacy evidence, Mr. Brassard identified three species, as being hazardous to health or particularly destructive to property, carpenter ants, pharaoh ants and the fire ant. 199/ The other species are considered primarily nuisance pests. 200/ Against two of these species, the pharaoh ant and the fire ant, there is no evidence that sweet-liquid sodium arsenate ant baits are effective. 201/ With respect to the carpenter ant and the remaining species, the record does

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197/ See EPA Ex. 217, for the label for the ORTHO ant killer, which is the same product as the TAT ant trap with propoxur, EPA Reg. No. 506-137. See EPA Initial Br. at 138, n. 87.

198/ See e.g., publication by Division of Agricultural Sciences, University of California, Leaflet 2526, in EPA Ex. 297.

199/ EPA Ex. 119 (16-32).

200/ EPA Ex. 119 (p. 33).

201/ Senoret makes no claim that the sodium arsenate ant bait products are effective against fire ants. There is one study identifying sodium arsenate as effective against the pharaoh ant in hospitals. In that case, however, a protein bait such as beef or liver, possibly mixed with honey, was recommended. See translation of EPA Ex. 243 (pp. 7-8). That translation is made a part of the record as EPA Ex. 243A. Dr. Trainello found that bait efficacy tests on the pharaoh ant done with boric acid yield positive results (but slow eradication). Senoret Ex. 88. See also Senoret Ex. 107 (identifying four products, none of them sodium arsenate ant baits, as effective against the pharaoh ant, including a mint apple jelly plus boric acid bait). As to this species, then, there is evidence of the effectiveness of boric acid but none of a sweet-liquid sodium arsenate product.

show that sodium arsenate is effective against sweet-eating ants where small populations are present, but fails to demonstrate that sodium arsenate is any more effective in this respect than the alternative ant bait products.

Senoret argues that the toxicity of the alternative products to humans cannot be determined unless the inert ingredients are known. 202/ Again it argues that was deprived of due process on this issue by not being allowed to effectively cross-examine on the identity of the inert ingredients in the alternative formulation, since the information was not disclosed to it. 203/

First, to be noted is that disclosure of the inert ingredients is not necessary to evaluate the comparative toxicity of the active ingredients in the formulations. If this alone is taken into account, all of the alternative products appear to be considerably less toxic than the sodium arsenate formulations. 204/

Senoret argues that the AAPCC data shows that in the years 1986 and 1987, boric acid and borax were responsible for six major effects medical

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202/ Senoret Initial Br. at 95-97.

203/ Senoret Reply Br. at 7-8.

204/ EPA Ex. 1 (pp. 60-61). Senoret argues that the LD_{50} for the other products is not comparable with the LD_{50} for sodium arsenate because they were done on the rat. Initial Br. at 14, Reply Br. at 14. But it would also be misleading to use the rat data for sodium arsenate if the rat has a metabolism for arsenic that is peculiar to it. See supra, p. 18. The rat was selected as the general test species because it was considered to be a useful model for estimating toxicity in man. In the case of arsenic, the hamster was preferred as the animal to make this estimate. EPA Ex. 5 (p. 111). Therefore, it would seem that the hamster data for arsenic is useful in estimating human lethality even though the other values are based on rat studies.

outcomes in 4,450 reported exposures, and carbomates, which include bendiocarb and propoxur, were responsible for 19 major medical outcomes. 205/ The record, however, shows that boric acid is, in fact, less toxic than sodium arsenate. 206/

With respect to the alternative formulations, it is true that they can also contain toxic inert ingredients. 207/ The EPA had Mr. Blondell testify that he examined the confidential ingredients statement of the alternatives and concluded that they are all considerably less toxic than Terro ant killer. 208/ I find that this evidence is of no weight because Senoret was deprived of effective cross-examination on the issue. 209/ I find, however, that no prejudical error has been committed, because the record is still adequate for decision on the issue.

First, it should be noted that as to two of the alternative products any hazard from a toxic inert ingredient, assuming such ingredient was

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205/ Senoret Initial Br. at 29-30.

206/ See Tr. 1299-1304, see also infra, p. 73, n. 211.

207/ For example, the label for the Antrol ant killer (1.0% propoxur as AI) discloses that the product contains the inert toxic ingredient formaldehyde. See EPA Ex. 217. At least as to this product, then, Senoret had notice of the identity of a toxic inert ingredient although not of the amount in the formulation. The absence of any such disclosure on the approval labels for the other alternatives suggests that they did not have any toxic inert ingredients. See 40 C.F.R. § 156.10(g)(7).

208/ EPA Rebuttal Ex. 1 (pp. 5-6), Tr. 3649-3665.

209/ I am not striking Mr. Blondell's testimony because he was testifying from personal knowledge of what he found in the files. Nevertheless, Senoret was entitled to cross-examine to determine whether Mr. Blondell had overlooked any relevant factors or made a mistake in his assessment of the toxicity of the alternative formulations.

present, would be minimized by the fact that they are sold in child-resistant packages. 210/ Most important, on this issue of whether available alternatives are more unsafe than the sodium arsenate ant bait products, the EPA has met its burden by showing that the products have been safe enough to be registered. It is Senoret's burden to show that notwithstanding their registration, there are hazards associated with the alternative products that should be considered in determining the benefits of the sodium arsenate ant bait products. It is not sufficiant to cite the number of exposures reported to the AAPCC for borates/boric acid and carbimates insecticides/pesticides. We cannot tell from this to what extent, if at all, the figures reflect exposures to alternative ant baits with these active ingredients. If these alternative formulations do present some special hazard, however, it would seem that there would be public information bearing specifically upon them just as there has been public information relating to the hazards of the sodium arsenate ant bait formulations. The record, however, is devoid of such information. 211/

In sum, Senoret in arguing that the alternative formulations may be more toxic than the sodium arsenate ant bait products has raised only

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210/ See labels for Ortho ant bait killer (the same product as the TAT ant trap, containing 0.25% propoxur), and for the Black Flag ant control system (containing 0.5% chloyriprifos as the active ingredient). EPA Ex. 217.

211/ As to boric acid, in fact, the record contains specific information that boric acid ant baits have not posed the same problem as the sodium arsenate ant baits. Dr. Litovitz made a study of the clinical manifestation of toxicity in boric acid ingestion. None of the cases studied reflected exposure to a boric acid bait product. Tr. 1289, 1302.

a specter and not a matter of substance. I find no prejudicial error in the refusal of the EPA to make the confidential formula statements available. 212/

I further find, on consideration of the entire record, that it is not likely that there will be any increased safety hazard in cancelling the sodium arsenate ant bait products.

C. The Economic Importance of Cancelling the Sodium Arsenate Ant Bait Products

The EPA argues that the economic impact of cancelling the sodium arsenate ant bait products is negligible because there are numerous alternative ant products which are marketed at prices comparable to the sodium arsenate ant bait products. 213/ The availability of equally effective numerous alternative ant bait at comparable prices, I find is supported by the record. 214/ The one point raised by Senoret that merits more specific consideration is their objection to the EPA's argument that sodium arsenate ant bait products have a small share of the market. 215/

212/ If the Administrator disagrees with my decision on this issue and finds that Senoret has been prejudiced by being denied cross-examinaton on the inert ingredients in the alternative formulations, it is recommended that he remand the matter and make this information available to Senoret in camera. The Administrator can frame the terms of the protective order, or he can leave the terms to the discretion of the Presiding Officer.

213/ EPA's Initial Br. at 133-141, Reply Br. at 97-102.

214/ See Mr. Dumas' testimony, EPA Ex. 214. Senoret argues that cancelling the sodium arsenate ant bait products will cause consumers to turn to the more costly pest control operators. The alternative formulations identified here appear to be sold to consumers.

215/ Senoret's Reply Br. at 59-60, responding to the EPA's Initial Br. at 137-140.

Mr. Dumas estimated that between 25 and 30 million packages of bottles of ant baits are distributed annually to wholesalers or retailers in the United States. He used distribution figures from the confidential annual reports each establishment producing and selling or distributing pesticides must file with the EPA (hereafter referred to as "§ 7 data"). 216/ Quantities are most typically supplied in pounds or gallons. 217/ Quantities for all but one of the products listed in Mr. Dumas' Table I were taken from this § 7 data for Mr. Dumas' calculation for 1987. 218/ Mr. Dumas took the quantities reported in pounds or gallons and converted the data to a number of packages depending on the package size shown in the labeling. 219/ Mr. Dumas' total, however, also included figures for a few other products not shown in Mr. Dumas' Table I. 220/ His methodology on its face seems suficiently precise to give an approximation of the total market for ant bait products in 1987, but the figures themselves are subject to a vital defect. The underlying § 7 data was simply not made available to Senoret for purposes of testing the accuracy of Mr. Dumas' calculations. The EPA refused to

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216/ EPA Ex. 214 (pp. 7-8); The information is required by FIFRA, § 7 (c), 7 U.S.C. 136e(c); The regulations are at 40 C.F.R. Part 167.

217/ Tr. 3924 (in camera). While the EPA counsel insisted that Tr. 3889-3969 should be put in camera, I find that the information disclosed in this decision from these pages need not be put in camera. This is also true of the other citations to in camera testimony herein.

218/ Tr. 3747-3751 (in camera). Data for that company, however was used for 1986. Tr. 3740-3747, in camera. Other sources were also used in some cases. Tr. 3740-3751 (in camera).

219/ Tr. 3752-3756, in camera.

220/ 3763-3771, in camera.

disclose the data even in camera. 221/ The confidential nature of the data is no excuse for the EPA's conduct. If it wanted to put in such data, the EPA should have taken in advance the necessary steps to comply with the statutory requirements for public disclosure or whatever was considered necessary for in camera disclosure. 222/ Denying the underlying data to Senoret fatally undermines the credibility of Mr. Dumas' figures derived therefrom. 223/ Accordingly, I am disregarding Mr. Dumas' calculations derived from § 7 data not disclosed or known to Senoret. 224/

221/ Tr. 3716-3726, 3942-3943. The confidentiality of § 7 data is specifically provided for in the regulations, which state that availability of the information to the public is governed by 40 C.F.R. Part 2. See 40 C.F.R. § 167.5(d). When one examines Part 2, the only provision found is the language taken from FIFRA § 10(b) and (d)(2), 7 U.S.C. 136h(b) and (d)(2), that information may be disclosed at a public hearing or in findings of fact issued by the Administrator. See 40 C.F.R. § 2.307(h)(4). As to production data, however, public disclosure can be made only after the submitter has been given prior notice. See FIFRA, § 10(d)(3), 7 U.S.C. 136h(d)(3). Nothing is said either in the rules or statute about in camera disclosure under suitable protective provisions in an administrative proceeding.

222/ Supra, n. 221.

223/ Even the limited cross-examination afforded Senoret disclosed some flaws in his calculation. See Senoret's Initial Br. at 102-103.

224/ I am not, however, striking these calculations from the record, because Mr. Dumas' again was testifying as to what he found from his personal knowledge of the reports. The reliability of the data and its weight, therefore, depends upon the accuracy and completeness of Mr. Dumas' reading of the § 7 data and of his calculations, as to which matters Senoret could not really inquire into.

Again, I find, however, that even though there are no reliable figures on the actual market shares of these sodium arsenate ant bait products, the record is still adequate to make a determination that cancellation will not result in any significant economic impact upon consumer.

Mr. Dumas testified that the alternative ant bait products are marketed at competitive prices throughout the United States. 225/ He stated further that sodium arsenate's small market share would most likely translate into slight increases in demand for each of alternative ant baits. Disregarding Mr. Dumas' characterization of the 1.2 million bottles of sodium arsenate ant bait products sold in the United States in 1987, as representing a "small" market share, I find the rest of Mr. Dumas' reasoning as persuasive evidence of why the cancellation of the sodium arsenate ant bait products is not likely to have any significant economic effect upon the consumer. Mr. Dumas stated as follows: 226/

> The availability of numerous alternative ant baits implies that the demand for the individual products is very elastic (i.e., price responsive). Therefore, attempts to increase the price of an alternative would result in the loss of market share for the producer of that alternative. Another factor to support the minimal price impact conclusion is that the volume of active ingredient used in the production of ant baits represents a small portion of the total production of each active ingredient; therefore, the price of the active ingredients will not be significantly affected. The implication of this factor is that the cost to produce additional bait stations is not likley to change within the relevant range of production. These factors together indicate that minimal price increases, if any, would be expected for individual ant bait products.

225/ EPA Ex. 214 (p. 9 and Tables 1, 2 and 3).

226/ EPA Ex. 214 (pp. 10-11).

> Within the ant bait market, the quantity of packages sold is not expected to change significantly if sodium arsenate ant baits are not longer available. It is logical that an individual who is predisposed to using ant bait products for minor ant infestations will continue to do so even when the products he normally uses is no longer available. The fact that consumers do not typically have efficacy information on any of the products available gives further credence to this assumption. The substitution by consumers of alternative ant baits for sodium arsenate ant baits is especially likely given that the prices of the most frequently marketed alternatives are similar to sodium arsenate.

Senoret argues that Mr. Dumas did not take into account the effect of cancellation on Terro's largest market, the North Central states of Wisconsin, Minnesota, Illinois and Iowa. 227/ The record, however, supports the finding that Mr. Dumas' analysis holds true generally for these states as well. 228/ Senoret also argues that Mr. Dumas knew nothing about whether the producers of the alternative bait products would have the production capacity to satisfy the increased demand caused by the removal of the sodium arsenate ant bait products. The market, however, represented by 1.2 million bottles on its face does not appear to be so large as to indicate that these alternate ant bait producers cannot satisfy it. Indeed, Mr. Dumas' figures show that ant baits are

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227/ Senoret's Initial Br. at 98. These four states account for between 38-40% of Terro's sales. Tr. 1817.

228/ Of the ten stores surveyed by Mr. Dumas in the North Central states (6 in Minnesota, 2 in Wisconsin and 2 in Illinois), six carried one or more of the alternative ant bait products, and one (in Green Bay, Wisconsin) did not carry Terro. While this is very limited information, it does indicate the presence of alternative products in that area at competitive prices. I would hesitate to draw any conclusion about market shares from Mr. Dumas' sample since it was not intended to be a statistically designed random sample. Tr. 3823, 3871-3872. For the same reason, it would be unwarranted to infer that because Terro was the only product sold in the two stores called on in Jerryville, Illinois, the alternative products were not available in that particular locality.

only a very small percentage of the household insecticide market. 229/ Leading companies in this market also distribute alternative ant bait products and they appear to be much larger than any of the producers of sodium arsenate ant baits. 230/

Accordingly, I conclude that consumers will have alternative ant bait products available at competitive prices if sodium arsenate is cancelled.

Senoret would also include in evaluating the benefits of sodium arsenate ant bait products, the costs of consumers if they had to turn to pest control operators as an alternative to controlling ants. 231/ I find that argument unpersuasuve because it assumes that the alternative ant bait products are not as effective as sodium arsenate to control ants, which assumption is not established by the record. 232/

The above evidence is sufficient to establish that consumers will suffer no adverse economic consequences as a result of cancelling the registration of these sodium arsenate ant bait products. Whether the share of the ant bait market of these sodium arsenate ant bait products is greater or less than the 4.8% found by Mr. Dumas is not material. I

229/ Mr. Dumas estimated total U.S. consumer expenditures in 1987 for household nonplant insecticides at 373 million. EPA Ex. 214 (p. 4).

230/ See e.g., EPA Ex. 307 (Table 2-18) giving U.S. sales of household insecticides by Boyle-Midway (manufacturers of Antrol Ant Killer, and Black Flag Ant Control system) and Chevron Chemical Co. (distributor of Ortho Ant Killer Bait). See EPA Ex. 217.

231/ Senoret's Initial Br. at 100.

232/ Supra, pp. 66-67.

find, therefore, that Senoret has not been prejudiced by its denial of effective cross-examination of Mr. Dumas on that issue. 233/

V. Conclusion

On examination of the entire record, and of the briefs of the parties and for the reasons stated, I find that the risk of the use of the sodium arsenate ant bait products outweighs the benefits of their continued use, and that these products should be cancelled. 234/

VI. ORDER

The registration of all pesticide products containing sodium arsenate issued under the Federal Insecticide, Fungicide and Rodenticide Act, and registered for use other than as a wood preservative, are hereby cancelled.

Gerald Harwood
Chief Administrative Law Judge

DATED: May 22, 1989
Washington, D.C.

233/ If the Administrator disagrees with my conclusion as to the materiality of the market share data, I recommend again that the matter be remanded with directions to make the underlying § 7 data available to Senoret in camera.

234/ The Administrator's Notice was directed to the cancellation of the registration of all inorganic arsenical pesticides registered for uses other than as a wood preservative. All products covered by the Notice, however, except for these sodium arsenate ant bait products have been cancelled by operation of law by the failure of the parties to file objections or by withdrawal of objections. The order, accordingly, is directed solely to the sodium arsenate ant bait products.

UNITED STATES ENVIRONMENTAL PROTECITON AGENCY

BEFORE THE ADMINISTRATOR

89 MAY 22 A9:31

In the Matter of Protexall Products, Inc., et al. Petitioners	)	FIFRA Docket Nos. 625, et al.

CERTIFICATION OF TRANSCRIPT

Pursuant to 40 CFR 164.82, I hereby certify that the foregoing 3993 pages of transcript corrected pursuant to my order of April 12, 1989 is a true transcript of the testimony offered and received at the hearing.

The following pages of transcript are in camera: 1686-1700, 1792-1794, 1819-1822, 2124-2125, 2641-2712, 2822-2856, 2957A-3059, 3089-3091, 3500-3509, 3529-3547, 3625, 3661-3663, 3727-3801, 3860-3870, 3888-3983.

I further certify that the following exhibits accompanying the transcript are all the exhibits introduced at the hearing:

1. Joint Exhibit No. 1
2. EPA (Respondent's) Exhibits Nos. 1, 1a, 2-146, 146a, 146b, 146c, 146d, 147, 147d, 148-156, 156a, 157-214a, 214b, 214c, 214d, 215-234, 236, 238-243 & 243A, 245, 246, 248-258, 260-290, 292-313.
3. EPA Rebuttal Exhibit No. 1.

4. EPA Cross-Examination Exhibits Nos. 1-38.

   The following EPA Exhibits are in camera: EPA Exhibit Nos. 1a, 159, 214a, 238, 248, 252, 277, 280 and 281; EPA Cross-Examination Exhibit No. 7.

5. Senoret (Petitioner) Exhibit Nos.: 1-5, 12-72, 72a, 72b, 72c, 73-84, 86-140; Petitioner's Exhibit No. 66 is in camera.

6. Senoret (Petitioner) Cross-Examination Exhibit Nos. 2-25, 27-33, 35-42, 44-52.

7. Senoret (Petitioner) Cross-Examination Exhibit Nos. 44, 45 and 48 are in camera.

Gerald Harwood

Gerald Harwood
Chief Administrative Law Judge

Dated: May 22, 1989
Washington, D.C.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of	)	
	)	
Protexall Products, Inc., et al.,	)	FIFRA Docket No. 625, et al.
	)	
Petitioner	)	

ORDER DENYING RESPONDENT'S MOTION TO ADMIT INTO EVIDENCE CERTAIN EXHIBITS

During the hearing, I rejected evidence offered by the EPA through Mr. Brassard, an entomologist for the EPA, consisting of certain memoranda prepared by Mr. Brassard and containing summaries of his telephone conversations with certain individuals ("Declarants"), concerning ant control with various substances, including sodium arsenate. These memoranda were as follows:

EPA Ex. 235 - Memo from Brassard to Dr. Roger Akre.

EPA Ex. 237 - Memo from Brassard to Doug Mamphe.

EPA Ex. 244 - Memo from Brassard to Dr. Ted Granofsky.

EPA Ex. 247 - Memo from Brassard to George Rambo.

EPA Ex. 259 - Memo from Brassard to Dr. Clifford Lofgren.

EPA Ex. 291 - Memo from Brassard to Dennis Edwards. 1/

1/ Transcript of proceedings ("Tr.") 2481-2490.

The EPA has moved to have these exhibits admitted. The motion is opposed by Petitioner Senoret and both parties have briefed the question. 2/ On consideration of the briefs of the parties and for the reasons noted below, the motion is denied.

Each memorandum, entitled "Record of Communication," consists of the major points of telephone conversations between Mr. Brassard and the Declarant, to whom the memorandum was sent and who signed and dated the memorandum and made any corrections, as requested in the attached cover letter from Mr. Brassard. Each memorandum was prepared by Mr. Brassard and typed, with the exception of page three of EPA Exhibit 234, which was handwritten by Mr. Brassard. 3/ The corrections by the Declarants were handwritten by them onto the memoranda. The text of the memoranda consists of observations and opinions of the Declarants concerning use and efficacy of ant control with several substances and with various methods and different species of ants. With the exception of EPA Exhibit 291, all of the memoranda mention use or efficacy of sodium arsenate ant baits, the continued registration of which is being challenged in this proceeding.

While the memoranda were signed and corrected by the Declarants, they were not sworn to by the Declarants and did not constitute a complete

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2/ EPA's Brief in Support of Evidence, filed March 22, 1989 (hereafter "EPA's supporting Br."), Petitioner's Brief in Opposition to the EPA' Offer of Evidence, filed April 3, 1989 (hereafter "Pet. Opp. Br."), and the EPA's Reply to Senoret's Brief in Opposition to the EPA's Offer of Evidence, filed April 4, 1989 (hereafter "EPA's Reply Br.").

3/ Tr. 2620.

record of the actual conversation that took place. Declarants were not called as witnesses by Respondent and were not cross-examined. No evidence of the Declarants' qualifications as experts was presented by the EPA except for the testimony of Mr. Brassard 4/ and several publications of some of the Declarants. 5/

The EPA contends that the memoranda are admissible as "relevant, competent and material" evidence under 40 C.F.R. § 164.41(a), citing Richardson v. Perales, 402 U.S. 389 (1971). That case, however, is clearly distinguishable.

Richardson involved a hearing on a claim for social security disability benefits and the Court held that a written report by a licensed physician who has examined the claimant and who sets forth in his report his medical finding in his area of competence may be received as evidence in a disability hearing and, despite its hearsay character and absence of cross-examination, may be relied upon to deny the claim. 6/

First to be noted is that Richardson involved medical reports, prepared by several physicians, which were presented at the hearing. Each physician had personally examined the claimant, and the reports were detailed, routine, standard, and consistent with each other. 7/ The

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4/ Tr. 3453-3454, 3497 for Dr. Roger Akre; Tr. 3584-3585, 3203-3204 for Doug Mamphe; Tr. 3405 for Dr. Ted Granovsky; Tr. 3583 for George Rambo; Tr. 3424-3425, 2493, 2540, 2594 for Dr. Clifford Lofgren; and Tr. 3586-3587 for Dennis Edwards.

5/ EPA Exs. 233, 297, 301 for Dr. Akre; EPA Exs. 275, 252 for Dr. Granovsky; EPA Exs. 264, 266, 267 for Dr. Clifford Lofgren.

6/ Richardson v. Perales, 402 U.S. at 402.

7/ Richardson v. Perales, 402 U.S. at 404.

Court specifically pointed out that "[c]ourts have recognized the reliability and probative worth of written medical reports even in former trials and, while acknowledging their hearsay character, have admitted them as an exception to the hearsay rule." 8/ That is not true of the memoranda in the present case. While such records of communication may be commonly used by entomologists, they are not standard as evidence in administrative proceedings. In Richardson, "the Court laid great stress on the fact that the reports were independent medical reports routinely prepared and submitted in disability cases." 9/

Second, as Senoret correctly points out, each of the examining physicians gave an independent report on the condition of the claimant in Richardson. Here, the memoranda were not independently produced. Rather, they are statements by Declarants of the efficacy and use of various ant control pesticides supplied after discussion with Mr. Brassard. Although, the memoranda were examined by Declarants, they do not in themselves disclose the full details of Mr. Brassard's conversation with Declarants.

Third, in Richardson there is no evidence that any of the physicians had any personal interest in the matter. The Court dismissed the fact that each physician was paid a fee as creating any bias in favor of the party who paid the fee. On the other hand, the circumstances with some of these memoranda are such that the possibility of bias cannot be so

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8/ Id. at 405. See also Fed. R. Evid. 803(4).

9/ Calhoun v. Perales, 626 F.2d 145, 149 (9th Cir. 1980), citing Richardson v. Perales, 402 U.S. at 402-407.

readily dismissed. For example, Dr. Akre stated that he had developed an effective poisoned ant bait for carpenter ants and was planning to market it. 10/ Under these circumstances, Dr. Akre may not be completely objective in evaluating a competing product. Nor can it be overlooked that pest control operators may prefer their methods and not be favorably inclined towards a product which is sold for use by the homeowner, such as the sodium arsenate ant baits. The lack of cross-examination precluded Senoret from probing into the possible bias of these witnesses.11/

Finally, there does not appear to be any compelling need for the EPA to rely on this type of information, such as apparently exists in the case of written physician's reports in determining social security disability claims. The EPA had available to it efficacy studies, treatises and other writings, as well as governmental publications, all of which were relied upon by Mr. Brassard. Indeed, the memoranda are used only to shore up Mr. Brassard's own opinion. 12/

The EPA also relying on Richardson, says that Senoret had the opportunity to cross-examine the Declarants through the power of subpoena,

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10/ EPA Ex. 235.

11/ It should be noted that Mr. Brassard himself was not wholly free from the appearance of being biased against the efficacy of sodium arsenate. See Initial Decision at p. 58. This could also have affected the opinions elicited from the Declarants.

12/ Tr. 3621. The Kliever testimony in Ciba-Geigy Corp., et a., FIFRA Docket Nos. 562, et al, incorporating information obtained from calls or visits to golf course or sod farm users and to a few extension entomologists, cited by EPA, is distinguishable because no objections were raised to its admissibility.

but impliedly waived such opportunity by failing to call the Declarants as witnesses. I disagree. Again, Richardson is plainly distinguishable. The medical reports in Richardson bore certain indicia of trustworthiness. That is not true of these memoranda for the reasons already noted. Further, to accept the EPA's argument would be to sanction the admissibility of all kinds of hearsay statements by the EPA, placing the burden on the other party to protect itself by discovery and by calling the Declarants as possible adverse witnesses, a result which would not only promote the use of discovery in these proceedings but would be a convenient way of increasing the burden of litigation for the opposing party. I find it difficult to believe that the EPA would accept similar written statements under such conditions if Senoret had sought to introduce them.

Finally, the EPA argues that hearsay can never be rejected and that all objections go only to its weight. Again, I disagree. Where it would be clearly unfair to rely on hearsay statements, and I find that is true of these memoranda, they should be excluded from the record. 13/

For the reasons above stated, the EPA's motion is denied.

Gerald Harwood
Gerald Harwood
Chief Administrative Law Judge

DATED: May 22, 1989
Washington, D.C.

13/ I am not striking any portion of Mr. Brassard's testimony except the references to the rejected exhibits. His testimony, however, will have to be evaluated without the support these exhibits give to it.