UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

RECEIVED BY OALJ
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In re FIFRA Section 6(b) Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products	)))))	FIFRA Docket No. 661

MOTION FOR AN EXPEDITED DETERMINATION THAT EPA'S EXISTING STOCKS DECISION IS WITHIN THE SCOPE OF THE HEARING

In its February 5, 2013 Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products ("NOIC"),[1] the Environmental Protection Agency ("EPA" or "the Agency") asserted, among other things: (1) that, if the Agency succeeds in cancelling the subject registrations, the Agency has "determined" that it will not permit those persons in possession of the cancelled products to "sell through" their existing stocks;[2] and (2) that Reckitt Benckiser LLC ("Reckitt" or "the Company") may not challenge this purported determination in the Section 6(b) hearing. 78 Fed. Reg. 8123, 8126-27 (Feb. 5, 2013). Reckitt believes that it was improper for EPA to make a final determination that applies to existing stocks of registered pesticide products that have not been cancelled and that, in any event, the determination that EPA made here is wrong. Moreover, EPA may not lawfully preclude Reckitt from obtaining a hearing concerning objections to EPA's stated position on existing stocks, nor

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1 The NOIC seeks to cancel the registrations of 12 consumer-use rodenticide products (the "Subject Products") registered by Reckitt. The NOIC also denied the applications for registration of two additional rodenticide products that Reckitt submitted to EPA. 78 Fed. Reg. 8123 (Feb. 5, 2013).

2 Existing stocks of cancelled pesticides are those products that were "released for shipment" under FIFRA before the effective date of cancellation. NOIC at 8126.

may EPA prohibit the presiding Administrative Law Judge ("ALJ") or the Environmental Appeals Board ("EAB") from addressing existing stocks as part of an initial or final decision. The Company therefore challenged EPA's positions on both existing stock issues in its Request for Hearing and Statement of Objections ("Statement of Objections"), Docket ID: EPA-HQ-OPP-2013-0049, and the Company intends to present evidence on these issues in this case.

Reckitt believes that the efficiency of the hearing process will be served by a prompt ruling that the Company's objections to EPA's existing stocks determination are within the scope of the cancellation hearing. Reckitt therefore respectfully requests that this Tribunal issue an order on an expedited basis affirming that Reckitt's objections to EPA's purported determination concerning existing stocks are within the scope of the hearing to which Reckitt is entitled pursuant to Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") Section 6(b), 7 U.S.C. § 136d(b). 40 C.F.R. §§ 22.16(a); 164.60(a).

INTRODUCTION

For years, EPA has sought to avoid providing Reckitt with its statutorily mandated hearing to contest the Agency's proposed cancellations. EPA initially sought to effect a *de facto* cancellation of the Subject Products by threatening enforcement actions against any registrant who did not comply with the Agency's 2008 Risk Mitigation Decision ("RMD").[3] Reckitt successfully brought suit to enforce its right to a hearing and, in 2011, the Company secured an injunction barring EPA from using its enforcement power to compel compliance with the RMD.[4] *Reckitt Benckiser Inc. v. Jackson*, 762 F. Supp. 2d 34, 43 (D.D.C. 2011).

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[3] EPA issued a final Risk Mitigation Decision for Ten Rodenticides on June 24, 2008.

[4] The regulatory history is detailed on pages 5-13 of Reckitt's Request for Hearing and Statement of Objections.

EPA finally issued the NOIC in February 2013, but now seeks to punish Reckitt for seeking to exercise its right to a hearing under FIFRA (and to penalize retailers who have lawfully acquired the Subject Products) by refusing to allow the sale and distribution of existing stocks in the event of cancellation. 78 Fed. Reg. at 8126. Moreover, EPA is once again trying to deprive Reckitt of the hearing to which it is entitled under FIFRA by declaring that it has "determined not to include existing stocks as an issue in this hearing." 78 Fed. Reg. at 8126-27. Just as the court held that EPA could not effect a *de facto* cancellation of the Subject Products by refusing to proceed with the hearing that FIFRA requires, so too is it improper for EPA to pronounce, by administrative fiat, that the parties affected by its decision to bar the sell through of existing stocks may not challenge that determination through the FIFRA hearing process. EPA's assertion that it may exclude a decision articulated in the NOIC from the scope of a cancellation hearing is contrary to applicable law, prior EPA practice and previous decisions of this Tribunal. As such, it constitutes yet another overreach of the Agency's authority, an attempt to intimidate retailers who may lawfully continue to stock the Subject Products pending the outcome of a hearing, and another unlawful effort both to evade review and to deny Reckitt the full hearing that FIFRA provides.

ARGUMENT

I. Reckitt is Entitled to a Hearing on the Issue of Existing Stocks

A. Reckitt Has a Statutory Right to a Hearing on the Existing Stocks Issue

Section 6(d) of FIFRA describes the scope of a Section 6(b) hearing as any "issues raised by the objections filed by the applicant," or, if the hearing is called by EPA, those "issues stated by the Administrator." 7 U.S.C. § 136d(d). EPA made a determination in the NOIC with respect to existing stocks—it seeks to bar the "sell through" of these stocks. 78 Fed. Reg. at 8126-27. EPA's inclusion of the existing stocks determination in the NOIC makes the issue subject to

objections that any interested parties may raise in response to the NOIC. *See* 40 C.F.R. § 164.22 (requiring concise statement of objections "to an order of the Administrator of . . . his intent to cancel the registration"). Reckitt and three other interested parties filed hearing requests that include objections to EPA's existing stocks determination.[5] As a result, pursuant to FIFRA Section 6(d), the existing stocks sell through issue is within the scope of the Section 6(b) hearing. This conclusion is supported by the regulatory history of the Part 164 Rules of Practice Governing Hearings, which states that hearings initiated under Section 6(b) are intended to address issues raised in the NOIC and the objections filed in response. 37 Fed. Reg. 9476, 9477 (May 11, 1972) ("The issues to be considered in the hearing are defined by the order of cancellation or suspension or denial of registration and the objections thereto filed by the registrants or applicant.").

Reckitt is also entitled to a hearing on the existing stocks issue because it will be "adversely affected" by EPA's determination on the disposition of existing stocks. FIFRA Rules state that "A proceeding shall be commenced whenever a hearing is requested by a person adversely affected by" a NOIC. 40 C.F.R. § 164.20(a). Reckitt would be adversely affected by EPA's existing stocks determination for several reasons. First, it would leave Reckitt with product that it could not sell and for which it would have to arrange proper disposal, which would be expensive and time consuming for Reckitt and its customers. Second, if insulated from

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[5] Statement of Objections ¶¶ 43-44, 96-105; Letter from Bob Taylor, President & CEO, Do it Best Corp., to Hearing Clerk, U.S. Environmental Protection Agency, Office of Administrative Law Judges (Mar. 5, 2013) (requesting a hearing "to consider the particular hardship and damage that this [not permitting the sale of existing stocks] would cause") (Exhibit A); Letter from Mark K. Franks, Executive Vice President, Greater Cincinnati Northern Kentucky Apartment Association, to Hearing Clerk, U.S. Environmental Protection Agency, Office of Administrative Law Judges (Mar. 5, 2013) (Exhibit B); Letter from Gale Lively, Executive Vice President, Louisville Apartment Association, to Hearing Clerk, U.S. Environmental Protection Agency, Office of Administrative Law Judges (Mar. 5, 2013) (Exhibit C).

challenge in the cancellation hearing, EPA's determination with respect to the disposition of existing stocks would deter Reckitt's retailers and consumers from purchasing lawfully registered products. This could have negative long-term effects on the Company regardless of the outcome of the proceeding. Reckitt therefore has a right to a hearing on this issue.

B. EPA Lacks the Authority to Exempt the Existing Stocks Issue from the FIFRA Hearing

EPA lacks the authority to use the NOIC to exempt from the hearing issues that are otherwise properly within the scope of the hearing that FIFRA provides. In *In re Reduce Pre-Harvest Interval for EBDC Fungicides on Potatoes*, Docket No. EPA-HQ-OPP-2007-0181 (January 16, 2008 Order), *available at* http://www.epa.gov/oalj/orders/ebdc-scope-hg-011608.pdf ("*EBDC*"), EPA published a Notice of Hearing on Request to Reduce Pre-Harvest Interval for EBDC Fungicides on Potatoes in the Federal Register, and the Natural Resources Defense Council ("NRDC") filed a request for a hearing. *Id.* Among other things, the Notice of Hearing identified the applicant's pre-cancellation due diligence as an issue for the hearing. *Id.* EPA, the applicant, and another party later filed a motion to remove this issue from the case, and NRDC opposed the motion. Before the Tribunal ruled on the motion, EPA filed an amended Notice of Hearing that omitted the issue. *Id.* The movants argued that only the issues that EPA included in its Amended Notice of Hearing could be contested and that the ALJ's decision-making authority was limited to those issues. *Id.* NRDC responded that the Administrator's ability to identify the issues to be adjudicated under the FIFRA Rules did not empower the Administrator to remove issues from adjudication by amending the Notice of Hearing *Id.* The Tribunal agreed with NRDC, explaining:

> A Notice of Hearing, or an amendment thereto, is merely an announcement of an event and related information and has no binding legal effect . . . the regulatory requirement of the Administrator "to *specify* . . . the issues of fact and law to be

> adjudicated at the hearing." . . . does not empower the Administrator to exempt adjudication of issues through the Notice of Hearing procedure that are to be adjudicated under applicable law and regulations.

EBDC 1/16/2008 Order at 13. The Tribunal found that NRDC had brought the due diligence issue within the scope of the hearing by challenging it in its Request to Participate in the Hearing, and that EPA could not thereafter unilaterally exclude the issue by filing an Amended Notice of Hearing. *Id.* at 10, 12-14.[6] ("NRDC in its Request to Participate in the Hearing . . . challenged the determination of 'due diligence,' thereby raising the issue in this proceeding. Accordingly, the request to delete the 'due diligence' issue from the Pre-Hearing Order is denied."). Thus, despite EPA's assertions to the contrary, by announcing its purported existing stocks determination in the NOIC, EPA has raised the issue, and Reckitt has brought the issue into the scope of the hearing by challenging it.

C. The ALJ Has the Authority to Issue an Order that the Existing Stocks Issue is Within the Scope of the Hearing

As the Tribunal recognized in *EBDC*, the NOIC is merely an announcement of EPA's intentions and has no binding legal effect. *Id.* The authority to determine the scope of the hearing in light of the statutory and regulatory framework lies with the ALJ. *See* 40 C.F.R. § 22.4(c)(7); 40 C.F.R. § 164.40(d) (ALJ has authority to "hear and decide questions of facts, law, or discretion" and "to take actions and decisions in conformity with the statute or in the interests of justice"). The EPA staff engaged in drafting the NOIC are carrying out investigative and prosecutorial functions. *See* 5 U.S.C. § 554(d). Any statement in the NOIC regarding the role of the ALJ in adjudicating the matter is merely an advocate's position in the litigation; it is not a binding statement of the ALJ's role and is not entitled to deference.

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[6] The Tribunal also denied EPA's motion for reconsideration of this issue. *EBDC* 5/15/2008 Order, *available at* http://www.epa.gov/oalj/orders/ebd-creconsid-051508.pdf.

If the EPA staff engaged in investigating and prosecuting could issue a binding declaration in the NOIC regarding the scope of the hearing, that practice would violate the "separation of functions" principle embodied in 5 U.S.C. § 554(d) (barring any investigative or prosecutorial personnel from participating or advising in an adjudicatory determination except as witness or counsel in the hearing). *See EBDC* 1/16/2008 Order at 6 (describing NRDC's argument that using the Federal Register amendment procedure to "shield issues from judicial review violates the 'separation of functions' embodied in 40 C.F.R. § 164.7, which prohibits *ex parte* discussion of the merits between the 'Administrator' and trial staff"). Only the EPA Administrator is exempt from the general separation of functions requirements, 5 U.S.C. § 554(d)(2)(C), and this narrow exception does not authorize those EPA personnel who perform investigative or prosecutorial functions in the hearing to give direction to the presiding ALJ. EPA's statement in the NOIC that no hearing is available concerning its "determination" that it will not allow sell through of existing stocks is nothing more than a prosecutorial position, and it cannot constrain the presiding ALJ from making an independent determination concerning what FIFRA and the EPA Rules of Practice require.

EPA Rules state that the ALJ has authority to "hear and decide questions of facts, law, or discretion." 40 C.F.R. § 22.4(c)(7). As a result, "[i]f an allegation is made that the Administrator's delegate abused his discretion in making a determination . . . , <u>the ALJ has authority to rule on the allegation</u>." *EBDC* 1/16/2008 Order at 9 (rejecting EPA's attempt to use an Amended Notice of Hearing to exclude issues from the hearing) (emphasis added). Further, the ALJ has the power "to take actions and decisions in conformity with the statute or in the interests of justice . . . ." 40 C.F.R. § 164.40(d). In this case, EPA's arbitrary actions and the

interests of justice both support the ALJ's authority to consider the existing stocks issue in the cancellation hearing.

In its Statement of Objections, Reckitt contends that EPA articulated a determination in the NOIC with respect to existing stocks that was both punitive and arbitrary and capricious. Statement of Objections ¶¶ 103-05. EPA's attempt to bar Reckitt from disputing its existing stocks determination is a transparent effort to unjustly punish Reckitt (and any retailer that continues to stock and sell the Subject Products) for exercising its statutory right to a cancellation hearing. The punitive and coercive intent of this determination is illustrated by the generous sell-through periods that EPA recently granted to two rodenticide registrants who, on the eve of issuance of the NOIC, agreed to voluntarily cancel the registrations for their non-conforming rodenticide products. 78 Fed. Reg. 11881, 11884 (Feb. 20, 2013) (permitting indefinite sell-through for the registrant's customers and one-year sell through for the registrant for certain products); 78 Fed. Reg. 15949, 11950 (Mar. 13, 2013) (permitting the sale and distribution of existing stocks by the registrant until November 1, 2013 and by others until at least September 1, 2014). EPA's willingness to permit other non-conforming rodenticide products to be sold through highlights the arbitrariness of EPA's attempt to bar Reckitt, and Reckitt's retailers, from selling through their existing stocks. Accordingly, the ALJ must hear and decide the question of whether EPA has abused its discretion with respect to the existing stocks determination—otherwise there is no check on the Agency's ability to ignore or materially limit the hearing requirements of Section 6(b). *See EBDC* 1/16/2008 Order at 9 (holding that the ALJ had authority to rule on the allegation that the Administrator's delegate abused his discretion in making a determination as to the "due diligence" issue, citing 40 C.F.R. § 22.4(c)(7)).

II. EPA's Position is Inconsistent with Case Law and Prior Agency Actions

EPA relies on *In re Cedar Chemical Co.*, 2 E.A.D. 584 nn.7, 9, 1988 WL 525242 (June 9, 1988) (Decision of the Administrator), *aff'd Northwest Food Processors Association v. Reilly*, 886 F.2d 1075, 1078 (9th Cir. 1989), for the following proposition:

> It is settled law that existing stocks issues are not required to be a part of a cancellation proceeding, and that the treatment of existing stocks issues is only included as an issue in a cancellation proceeding when the Notice giving rise to the right to a hearing voluntarily identifies and includes existing stocks as an issue for examination.

78 Fed. Reg. at 8126. However, *Cedar Chemical* arose under markedly different factual circumstances and in fact supports including the existing stocks issue in Reckitt's hearing. *Cedar Chemical* suggests two preconditions for challenging an existing stocks decision: (1) the person or entity requesting the hearing must have an independent right to a hearing, and (2) the issue of existing stocks must be raised in the NOIC.[7] Both of the preconditions are met in this case; Reckitt is the registrant and therefore has an independent right to hearing, and EPA made an existing stocks determination in the NOIC.

In *Cedar Chemical*, EPA issued a Notice of Intent to Cancel a number of registrations, and the NOIC said nothing about existing stocks. 51 Fed. Reg. 36650, 1986 WL 111948 (EPA Oct. 14, 1986); *Northwest*, 886 F.2d at 1078. Two of the affected registrants, Cedar Chemical Corporation and Drexel Chemical Company, filed statements of objections. Prior to the hearing, a user group (American Frozen Foods Institute, or "AFFI") intervened. The two registrants

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[7] Reckitt does not concede that EPA may effectively bar a registrant from raising the issue of the disposition of existing stocks in a cancellation hearing merely by excluding any mention of the issue from the NOIC. However, in this instance, EPA explicitly raised the existing stocks issue in the NOIC, Reckitt has challenged EPA's determination, and that issue is therefore squarely before this Tribunal. Reckitt fully reserves its rights to ALJ review of any effort by EPA to bar sell-through of existing stocks, even if at some later point in this proceeding the Agency attempts to modify or otherwise amend its NOIC to somehow further its attempts to remove the subject from consideration by this Tribunal.

subsequently agreed to enter a settlement with EPA in which they voluntarily canceled their registrations and were permitted limited sell-through of existing stocks for up to two years.

AFFI objected to the settlement and sought a hearing with respect to the cancellation and the disposition of existing stocks. In reliance on *McGill v. Environmental Protection Agency*, 593 F. 2d 631 (5th Cir. 1979), the Administrator held that AFFI did not have independent "hearing rights under FIFRA" because there were no longer any registrations about which a hearing could be held.[8] In deciding that AFFI was not entitled to force EPA to hold a hearing on the issue of existing stocks, the Administrator asserted that non-registrant parties have no independent basis to demand a hearing on any issue, including existing stocks, when all affected registrants themselves already have agreed to cancellation.[9]

Here, unlike in *Cedar Chemical*, Reckitt is the sole registrant of the products at issue and, by timely filing its Statement of Objections, has challenged both the proposed cancellation and EPA's purported determination with respect to existing stocks. Reckitt therefore satisfies all of the conditions necessary to require a FIFRA Section 6(b) hearing regarding every aspect of the NOIC that adversely affects the Company and the status of the Subject Products. Further, unlike in *Cedar Chemical*, where a non-registrant intervening party sought to raise an issue not addressed in the NOIC, Reckitt is pursuing a hearing in part to present evidence on an issue that EPA specifically raised in the NOIC.

EPA relies on a single statement in a footnote from *Cedar Chemical* for its broad assertion that its ban on the sell through of existing stocks may be challenged in a hearing only

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[8] AFFI did not itself request a hearing under FIFRA § 6(b), but instead became a party when it subsequently intervened in the cancellation hearing requested by certain registrants. *Cedar Chemical*, 2 E.A.D. 584 n.10.

[9] Some of the products governed by the existing stocks provision were cancelled pursuant to a settlement with EPA, and others were previously cancelled by operation of law when the registrants failed to request a hearing. *Cedar Chemical*, 2 E.A.D. 584 n.6.

when EPA both includes the ban in the NOIC and then expressly states that the ban can be addressed in a hearing. 78 Fed. Reg. at 8126 (*citing Cedar Chemical*, 2 E.A.D. 584 n.7). However, EPA ignores the facts in *Cedar Chemical*, where the NOIC did not raise the existing stocks issue and the non-registrant parties trying to raise the issue were seeking to expand the scope of the hearing to cover issues not mentioned in the NOIC. As the court noted in *Northwest*, it would be "very unfair" to interested parties to include an existing stocks issue in the cancellation hearing without prior notice. In that case, "[t]he notice of intent to cancel did not even hint that NCAP's interests could be adversely affected by an existing stocks order resulting from the cancellation hearing," so the Administrator's decision that the issue was not legally a part of the cancellation hearing was reasonable. *Northwest*, 886 F.2d at 1078.

Here, in contrast, the issue the ALJ was trying to protect against in *Cedar Chemical* does not exist. EPA has placed Reckitt and other adversely affected parties on notice of the Agency's intentions concerning existing stocks, and Reckitt is duly challenging those intentions. As a result, unlike in *Cedar Chemical* and *Northwest* where a third party was trying to raise an issue not addressed in the NOIC, there is no risk here that Reckitt's interests can be adversely affected without its knowledge.

EPA's contention also is contrary to case law establishing that any issue that is identified in the NOIC is within the scope of a Section 6(b) hearing. In the same footnote of *Cedar Chemical* upon which EPA relies, the Administrator states: "Obviously, if an issue is identified in the cancellation notice, it fits within the framework of the proceeding and may be litigated in a hearing." *Cedar Chemical*, 2 E.A.D. 584 n.9. The same footnote further states: "In procedural terms, the notice serves much the same function as a complaint in any other administrative proceeding, and as such, it 'set[s] the standard of relevance which shall govern the proceedings

at the hearing.'"[10] *Id.*, *quoting In re Shell Oil Co.*, 1 E.A.D. 517, 1979 WL 52074 (EPA April 9, 1979) at *10-11 (internal citation omitted).

Both of these statements demonstrate that, if the NOIC contains an existing stocks determination, objections to that determination fall squarely within the scope of a Section 6(b) hearing requested by an adversely affected party. *See also EBDC* 1/16/2008 Order at 10 (holding the issue raised in an objection to the Notice of Hearing was properly within the scope of the proceedings). Thus, at most the portion of the *Cedar Chemical* decision cited by EPA stands for the unremarkable proposition that, for an issue properly to be part of a Section 6(b) hearing, that issue must be addressed in the NOIC and challenged in an affected party's request for a hearing. Here, those requirements are met: the NOIC for Reckitt's products contains an existing stocks determination, and the Company's Statement of Objections challenges that determination. This issue squarely "fits within the framework of the proceeding."

EPA's contention that challenging an existing stocks determination in a Section 6(b) hearing somehow requires a formal written invitation from the Agency is also inconsistent with prior case law in which existing stocks issues were considered without such an invitation. In the NOIC for inorganic arsenicals for non-wood preservative use, EPA determined that it would not permit the continued sale and use of the subject products beyond the cancellation date. 53 Fed.

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[10] In *Shell Oil*, the EAB held that objections raised in response to a NOIC must be relevant to the matters raised in that document. The objections at issue were submitted by a non-registrant, Carlos Amaya (representing a coalition of migrant farm workers), who argued that the conditional cancellation that EPA proposed should instead be an unconditional cancellation or, alternatively, contain more stringent restrictions. The EAB rejected Amaya's attempt to expand the scope of relief sought in the NOIC, describing the NOIC's role as "providing a framework for the remainder of the proceeding." Contrary to the objections at issue in *Shell Oil*, here Reckitt is a registrant that has filed timely objections to oppose the actions in the NOIC, including EPA's purported determination banning sell through of existing stocks. Reckitt is not attempting to expand the issues addressed in the NOIC; rather, it is objecting to the specific determination on the existing stocks issue set forth in the NOIC. *See EBDC* 1/16/2008 Order at 13-14 (distinguishing *Shell* because the party sought relief different from that sought in the NOIC).

Reg. 24787, 24794 (June 30, 1988). While EPA said that registrants with voluntary cancellations could petition the Agency to allow the continued sale and distribution of existing stocks, EPA did not specify whether the existing stocks determination could be challenged in a hearing by parties that were opposing the cancellations. Several registrants requested a hearing, and one of them, Senoret, presented evidence at the cancellation hearing.[11]

In its decision, the Environmental Appeals Board ("EAB") considered and ruled on the proper disposition of existing stocks even though the NOIC did not specify the issue as one that could be considered in a hearing.[12] *In re Protexall Products, Inc.*, 2 E.A.D. 854, 1989 WL 550929 at 25-26 (EPA July 26, 1989) (Exhibit D); 53 Fed. Reg. 24787, 24794-95 (June 30, 1988). EPA took a similar position in its cancellation of Toxaphene, stating that "The 30-day time period in which to request a hearing is applicable to all the regulatory actions proposed in this Notice, including . . . the existing stocks provisions . . . ." *See* Notice of Intent to Cancel or Restrict Registrations of Pesticide Products Containing Toxaphene, 47 Fed. Reg. 53792-93, 1982 WL 153737 (Nov. 29, 1982). Thus, prior EAB decisions and prior EPA practice align with the statutory language of FIFRA and establish that, contrary to EPA's assertions, merely including an existing stocks determination in a NOIC is sufficient to bring it within the scope of a hearing when a registrant timely files an objection to it.

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11 Four other registrants also requested a hearing, but Senoret was the only active party.

12 The EAB found that, based on the evidence in the record, Senoret had not met its burden of showing it should be permitted to sell existing stocks. Here, Reckitt asks for the same opportunity to prove its case as was provided to Senoret.

CONCLUSION

For the foregoing reasons, Reckitt respectfully requests a determination that EPA's purported existing stocks determination in the NOIC is within the scope of the hearing to which Reckitt is entitled under FIFRA.

Prior to filing this Motion, the undersigned contacted EPA as to the relief requested herein and EPA indicated that it opposes the Motion and intends to file a Response.

Dated: April 12, 2013

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Exhibit A

Do it Best Corp.

Products
Services
Solutions

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Ph: 260-748-5300
Fax: 260-493-1245
mail@doitbest.com

March 5, 2013

Hearing Clerk
c/o -U.S. Environmental Protection Agency
Office of Administrative Law Judges
1099 14th Street NW
Franklin Court Building
Suite 350
Washington, DC 20005

Via: Federal Express

Re: Hearing Request Concerning EPA Docket # EPA—HQ—OPP-2013-0049; Notice of Intent to Cancel Certain Rodenticide Bait Products

Dear Sir or Madam:

I am the President & CEO of Do it Best Corp., a member-owned cooperative of close to 4000 retail hardware, lumber and building materials dealers across the country. The independent member-owners of our cooperation strive each day to provide their customers with the solutions they need for everyday home improvement problems, including rodent control. I understand that the EPA is considering the cancellation of certain rodenticide baits, including the following:

- d-CON Mouse Prufe II (registration #3282-65)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00065-20081031.pdf
- d-CON Pellets Generation II (registration #3282-66)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00066-20081031.pdf
- d-CON Bait Pellets II (registration #3282-74)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00074-20120425.pdf
- d-CON Ready Mixed Generation II (registration #3282-81)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00081-20081031.pdf

Our members have safely sold and advised customers on the proper use of rodenticides since our company's founding nearly 70 years ago. Do it Best Corp. members sell d-CON products because they are among the most effective and affordable rodent control products on the market. We would be very disappointed to see the EPA ban these products, and I know our customers would as well.

Even more concerning, I understand that if EPA does ban these products, EPA does not intend to allow stores such as ours to sell their existing stocks of the d-CON products that we already have on hand. This would penalize both retailers and distributors like Do it Best Corp., who bought these products in good faith while they were still completely legal. If EPA is indeed moving in this direction, we respectfully request a hearing to consider the particular hardship and damage this would cause to retailers and distributors in the channels of trade.

Sincerely,

Bob Taylor
President & CEO

I hereby certify that I have provided copies of this letter by Federal Express to the people named below:

Cc:
James Jones
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Mail Code 7101M
U.S. Environmental Protection Agency
Ariel Rios Building
1201 Constitution Avenue N.W.
Washington, DC 20004

d-CON Rodent Control Products Regulatory Staff
c/o Reckitt Benckiser
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Exhibit B

Greater Cincinnati Northern Kentucky Apartment Association

Kenwood Executive Center • 7265 Kenwood Road, Suite 100 • Cincinnati, OH 45236
(513) 407-8612 • fax (513) 407-7868 • www.gcnkaa.org

March 5, 2013

Hearing Clerk
C/O U.S. Environmental Protection Agency
Office of Administrative Law Judges
1099 14th Street NW
Franklin Court Building
Suite 350
Washington, DC 20005

Via: United Parcel Service

Re: Hearing Request Concerning EPA Docket # EPA—HQ—OPP-2013-0049; Notice of Intent to Cancel Certain Rodenticide Bait Products

Dear Sir or Madam:

I write on behalf of the Greater Cincinnati Northern Kentucky Apartment Association. The members of our organization cover the full gamut of the apartment industry, from market rate to tax credit to senior and to affordable housing units. It is our mission to contribute our knowledge of the multi-family building and management to the best interest of those our members serve and perpetuate an environment favorable to apartment living. In my role, I am well versed in what it takes on a daily basis for landlords to provide a clean and safe home for people.

I understand that the EPA is trying to cancel certain rodenticide baits, including the following:

- d-CON Mouse Prufe II (registration #3282-65)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00065-20081031.pdf
- d-CON Pellets Generation II (registration #3282-66)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00066-20081031.pdf
- d-CON Bait Pellets II (registration #3282-74)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00074-20120425.pdf
- d-CON Ready Mixed Generation II (registration #3282-81)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00081-20081031.pdf

The Greater Cincinnati Northern Kentucky Apartment Association represents 157 Owner/management companies with 78,057 multi-family housing units in approximately 420 communities and/or scattered sites. Our members provide housing to residents and are responsible for maintaining a living environment that is clean and safe and affordable to our residents. It is especially important for maintenance staff to quickly and effectively respond to the presence of rats or mice in apartment homes and other buildings in the community. For our members and their tenants, d-CON products play an important part in ensuring the health and safety of their families. These products are affordable and they work.

Banning these products would cause real hardship to many of the members and tenants we serve, and I do not believe that the EPA has a good reason to take these products off the market. They seem to be determined to solve a problem that does not exist. If only professional pest control companies have access to the most effective rodent control products, tenants and property owners alike will have to bear additional expenses to keep infestations from occurring and to respond quickly when such problems do arise.

I understand that the EPA not only intends to ban d-CON, but also will not allow stores to sell these products to sell off any stocks they currently have on their shelves once the ban takes effect. This means that at any time, our members and families in our communities could be deprived without warning of their first line of defense against disease-bearing rats and mice.

I believe that the EPA's actions are unwarranted and that they should be required to make their case at a hearing before an Administrative Law Judge. I also think that a hearing needs to be held on these issues so that our members' needs can be considered.

Sincerely,

Mark Franks

Mark K. Franks
Executive Vice President

I hereby certify that I have provided copies of this letter by Federal Express to the people named below:

Cc:
James Jones
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Mail Code 7101M
U. S. Environmental Protection Agency
Ariel Rios Building
1201 Constitution Avenue N.W.
Washington, DC 20004

d-CON Rodent Control Products Regulatory Staff
C/O Reckitt Benckiser
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Exhibit C

Louisville Apartment Association
MEMBER NATIONAL APARTMENT ASSOCIATION
7400 South Park Place, Suite 1, Louisville, Kentucky 40222
Phone: (502) 426-6140 Fax: (502) 426-2148
E-mail: info@laaky.com Website: www.laaky.com

2013

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Chris Dischinger
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Martin Carney

March 5, 2013

Hearing Clerk
C/O U.S. Environmental Protection Agency
Office of Administrative Law Judges
1099 14th Street NW
Franklin Court Building
Suite 350
Washington, DC 20005

Via: Federal Express

Re: Hearing Request Concerning EPA Docket # EPA—HQ—OPP-2013-0049; Notice of Intent to Cancel Certain Rodenticide Bait Products

Dear Sir or Madam:

I write on behalf of the Louisville Apartment Association. The members of our organization cover the full gamut of the apartment industry, from market rate to tax credit to senior and to affordable housing units. It is our mission to contribute our knowledge of the multi-family building and management to the best interest of those our members serve and perpetuate an environment favorable to apartment living. In my role, I am well versed in what it takes on a daily basis for landlords to provide a clean and safe home for people.

I understand that the EPA is trying to cancel certain rodenticide baits, including the following:

- d-CON Mouse Prufe II (registration #3282-65)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00065-20081031.pdf
- d-CON Pellets Generation II (registration #3282-66)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00066-20081031.pdf
- d-CON Bait Pellets II (registration #3282-74)

Celebrating 47 Years

- Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00074-20120425.pdf
- d-CON Ready Mixed Generation II (registration #3282-81)
  - Label here: http://www.epa.gov/pesticides/chem_search/ppls/003282-00081-20081031.pdf

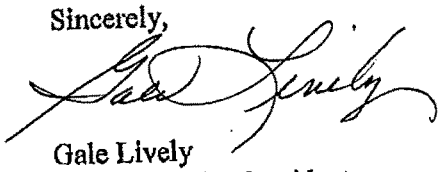
The Louisville Apartment Association represents 302 members and their 87,362 tenants. We provide housing to residents and are responsible for maintaining a living environment that is clean and safe and affordable to our residents. It is especially important for maintenance staff to quickly and effectively respond to the presence of rats or mice in apartment homes and other buildings in the community. For our members and their tenants, d-CON products play an important part in ensuring the health and safety of their families. These products are affordable and they work.

Banning these products would cause real hardship to many of the members and tenants we serve, and I do not believe that the EPA has a good reason to take these products off the market. They seem to be determined to solve a problem that does not exist. If only professional pest control companies have access to the most effective rodent control products, tenants and property owners alike will have to bear additional expenses to keep infestations from occurring and to respond quickly when such problems do arise.

I understand that the EPA not only intends to ban d-CON, but also will not allow stores to sell these products to sell off any stocks they currently have on their shelves once the ban takes effect. This means that at any time, our members and families in our communities could be deprived without warning of their first line of defense against disease-bearing rats and mice.

I believe that the EPA's actions are unwarranted and that they should be required to make their case at a hearing before an Administrative Law Judge. I also think that a hearing needs to be held on these issues so that our members' needs can be considered.

Sincerely,



Gale Lively
Executive Vice President

I hereby certify that I have provided copies of this letter by Federal Express to the people named below:

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Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Mail Code 7101M
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Washington, DC 20004

d-CON Rodent Control Products Regulatory Staff
C/O Reckitt Benckiser
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Exhibit D

C
2 E.A.D. 854, 1989 WL 550929 (E.P.A.)

United States Environmental Protection Agency (E.P.A.)
Office of the Administrator

IN THE MATTER OF PROTEXALL PRODUCTS, INC., ET AL.,

Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA Docket Nos. 625, et al.

July 26, 1989

Opinion by Ronald L. McCallum, Chief Judicial Officer:

FINAL DECISION

I. BACKGROUND

This cancellation proceeding was brought under section 6 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 7 U.S.C. 136d(b). The pesticide registrations at issue permit the household use of non-child-resistant baits containing sodium arsenate to kill ants. The risk-benefit assessment required under FIFRA involves a balancing of the risks to children associated with these ant baits against the benefits of continued use to control several household pest ant species. The ants involved are nuisance species and do not pose a threat to human health, food crops, or the integrity of buildings. Based on the hearing record and for the reasons set forth below, I conclude that Petitioners have failed to meet their burden of proving that the benefits of continued use of open sodium arsenate baits to control household ants justifies the risk to human health associated with the baits, particularly the risk to small children. [FN1]

A. Sodium Arsenate Ant Baits
Sodium arsenate ant baits are used primarily in and around homes for the control of small infes-

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tations of sweet-eating ants. These baits are formulated as sugar-based syrups. The syrup is applied to a "bait station," such as a piece of cardboard, wax paper, bottle cap, or food such as a cracker. The bait stations are placed around the house where ants are present. The theory behind the ant baits is that foraging worker ants will feed on the sweet bait, store it in their crops, and carry it back to the nest. At the nest, the theory goes, the worker ants will regurgitate the sweet liquid and feed it to other members of the colony, thereby killing the brood, other workers, and, perhaps most importantly, the queen. Initial Decision at 54-55. The specific sodium arsenate ant baits at issue in this proceeding are described in the Joint Stipulations as follows:

1. Terro Ant Killer, a liquid ant bait containing 2.27% sodium arsenate in a sweet liquid. This product is manufactured and formulated by the Senoret Chemical Company and is sold in one ounce and two ounce bottles. Since January 1, 1988, Senoret has marketed all of its Terro Ant Killer in bottles with a child-resistant cap. [FN2] Terro is sold with six cardboard squares recommended for use as bait stations. [FN3]

2. Jones Ant Killer, a liquid ant bait containing 1.5% sodium arsenate in a sweet liquid. This product is manufactured and formulated by Jones Products, Inc. and is sold in one ounce and six ounce bottles. Both sizes are sold with an accompanying bait station in the form of an open plastic cup. [FN4]

3. FATSCO Ant Poison, a liquid ant bait containing 3.0% sodium arsenate in a sweet liquid. This product is manufactured and formulated by FATSCO and is sold in a 0.5 ounce, a 0.75 ounce, and a 2.0 ounce bottle. FATSCO also sells an "ant cup," which the company recommends for use as a bait station in yards. [FN5] The 0.5 ounce bottle label also recommends the use of pieces of cotton as bait stations.

4. Ant Kill, a liquid ant bait containing 2.27% sodium arsenate in a sweet liquid. This product is sold by Protexall Products, Inc. in a two ounce bottle. [FN6]

B. The Notice of Intent to Cancel

On October 18, 1978, the Agency initiated a Special Review of all wood preservative and non-wood preservative uses of inorganic arsenicals based on a determination that these uses met or exceeded the risk criteria for oncogenicity, teratogenicity, and mutagenicity. 43 Fed.Reg. 48267.Acute toxicity did not become a serious concern to EPA until the Agency subsequently received evidence regarding the acute effects of arsenicals. Only the non-wood preservative arsenicals are at issue in this proceeding. [FN7]

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On January 2, 1987, the Agency issued a Notice of Preliminary Determination to cancel registrations of pesticide products containing inorganic arsenicals registered for minor [FN8] non-wood preservative uses, including registrations for ant bait products containing sodium arsenate. The risk assessment presented in the Preliminary Determination identified two primary hazards associated with these minor uses: oncogenicity for mixer/loaders and applicators, and acute toxicity to the general public resulting in a large number of accidental exposures. [FN9] The Preliminary Determination identified numerous effective, affordable alternatives for the arsenical of concern, and concluded that the risks posed by these arsenicals outweigh the benefits of continued registration. [FN10] Thus, the Agency proposed to cancel registrations for all minor non-wood preservative inorganic arsenicals.

After soliciting comments from the Secretary of Agriculture [FN11] and the Scientific Advisory Panel [FN12] as required by FIFRA, and after considering the views of registrants and other interested parties, on June 30, 1988, the Agency issued its Notice of Intent to Cancel (and to deny applications for) registrations for inorganic arsenical pesticide products for non-wood preservative use. 53 Fed.Reg. 24787.The arsenic compounds covered by the Notice are lead arsenate, calcium arsenate, sodium arsenate, sodium arsenite, and arsenic trioxide. [FN13]

The notice summarized the hazards associated with exposure to inorganic arsenicals, including oncogenicity, mutagenicity, teratogenicity, and acute toxicity. The most important risk posed by the sodium arsenate ant baits at issue here, however, is acute oral toxicity. The Agency relied in part on information from its Pesticide Incident Monitoring System (PIMS), which indicated that a significant number of poisoning incidents had occurred as a result of the accidental ingestion of insect baits containing sodium arsenite, sodium arsenate, and lead arsenate. [FN14] The majority of these incidents involved children. Indeed, the Agency concluded that exposure to sodium arsenate ant baits is the leading cause of child poisonings. [FN15] The Agency discussed the use of child-resistant bait stations as an alternative to cancellation, but Senoret indicated that this option was unacceptable despite its obvious risk reduction potential. [FN16] One arsenical ant bait, the Grant's Ant control product, which contains arsenic trioxide in a sealed metal container, was exempted from the Notice of Intent to Cancel because it was not found to pose a hazard to the public. 53 Fed.Reg. 24793.

C. Procedural History

Only registrants of non-child-resistant ant baits filed objections to the Notice of Intent to Cancel and requested a hearing. Of these registrants, Protexall, Jones, and FATSCO elected to be inactive

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parties, and Senoret was the sole party presenting evidence at the hearing to support the continued registration of the ant baits. [FN17] The Agency as "Respondent" in this proceeding supported cancellation of the registrations. The hearing commenced on January 23, 1989, and was closed April 27, 1989. At the hearing, Senoret and the Agency together called a total of 15 witnesses and generated a massive record, including approximately 600 exhibits and almost 4,000 pages of transcript. The trial judge, Chief Administrative Law Judge Gerald Harwood, provided a thorough and straightforward analysis of the evidence in his May 22, 1989 Initial Decision, in which he ordered cancellation of registrations for all pesticide products containing sodium arsenate. On June 12, 1989, Senoret filed exceptions to the Initial Decision. [FN18] On June 22, 1989, the Respondent EPA filed a response to Senoret's exceptions. [FN19]

II. LEGAL STANDARD

A. The Statutory Test

The statutory standard for pesticide registration requires that a pesticide perform its intended function without causing "unreasonable adverse effects on the environment."FIFRA § 3(c)(5)(C), 7 U.S.C. § 136a(c)(5)(C). The phrase "unreasonable adverse effects on the environment" is 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."FIFRA § 2(bb), 7 U.S.C. § 136(bb). The ultimate burden of proof—i.e., the risk of non-persuasion—remains at all times on the registrant. 40 CFR § 164.80(b).

FIFRA § 6(b), which specifically addresses cancellation, states that a notice of intent to cancel may be issued if:

> a pesticide or its labeling or other material required to be submitted does not comply with [FIFRA] *** or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment ***.

FIFRA § 6(b), 7 U.S.C. § 136d(b) (emphasis added). Although the labels for the sodium arsenate ant baits direct that the products be kept out of the reach of children, as discussed below the widespread and commonly recognized practice is contrary to this instruction. [FN20] Thus, it is not merely the label directions that determine the manner of use of the product to be considered in the risk analysis; instead, where "widespread and commonly recognized practice" differs from use as indicated on the label, the risk to be evaluated is the risk created by that actual use of the product. [FN21] Finally, as recently noted by the Fifth Circuit, cancellation is warranted only when the product "generally" causes unreasonable adverse risk (though not necessarily actual effects) to man or the environment. See Ciba-Geigy Corp. v. EPA, 29 ERC 1721, 1722 (5th Cir.

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June 2, 1989).

B. The Risk Warranting Cancellation

The basic statutory standard is that cancellation is required if continued use would cause "any unreasonable risk to man or the environment."FIFRA § 2(bb) (emphasis added). Although the Agency will not initiate steps leading to possible cancellation of a registered pesticide product unless it first determines that its use and resulting exposure pose a significant risk (for example, risk of "serious acute injury to humans," 40 CFR § 154.7(a)(1)), no specific threshold level of risk must be shown as a predicate for cancellation.

III. THE RISK OF CONTINUED USE

Judge Harwood devoted forty pages of his Initial Decision to a thoughtful and detailed analysis of the evidence presented regarding the risks associated with exposure to sodium arsenate ant baits. He concluded that a sufficient number of persons are put at risk to the adverse effects of arsenic poisoning and the discomfort and side effects associated with treatment to warrant cancellation of the registrations for the sodium arsenate ant baits unless the benefits of having them available exceed the risks. Initial Decision at 53. Except for a few instances (noted below), I am adopting Judge Harwood's factual findings on the risk issue, and I see no need to reconstruct the entire risk analysis. Instead, I will summarize the ALJ's findings for context and continuity and then address Senoret's exceptions to his risk analysis.

A. The ALJ's Findings

The ALJ's risk analysis focused on the effects of acute accidental oral exposure of children to sodium arsenate bait products. Initial Decision (pp. 13-14). Based on information obtained from the American Association of Poison Control Centers (AAPCC) and certain Regional Poison Control Centers, the ALJ concluded that there are a significant number of exposures of children to these ant bait products each year, exposures he characterized as "widespread." Id. at 52 n. 154.In 1987, the AAPCC reported 1475 exposures to Terro or Jones baits. Id. at 29.After deleting 11 cases in which some other substance as well as sodium arsenate was involved, more than 97% of these were accidental, and more than 85% involved children under the age of six (id. at 30), apparently because users are unable to keep the products out of the reach of small children. Id. at 53.The labels of these ant baits warn that the product (presumably both the bottle and the bait station) should be kept out of the reach of children and may be fatal if swallowed, but the ALJ found that these warnings do not prevent widespread accidental exposures to the products. Id. at 14, 52 n. 154.[FN22]

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The symptoms generally associated with arsenic poisoning can range from mild gastrointestinal illness, to very severe illness and even death. Initial symptoms include vomiting, diarrhea, and abdominal pain, and may be accompanied by chills, fever, headaches, and nervousness. Id. at 30.Fluids may also leak from the blood vessels into other tissues (referred to as "third-spacing"), resulting in low blood pressure and possible death if electrolytes and fluids are not replaced quickly. Id. at 30-31.In addition, heart abnormalities such as ventricular arrhythmias or cardiac arrest and pulmonary edema and acute respiratory failure can occur. Id. at 31.Diminished renal function or failure, liver damage, and central nervous system injury such as toxic delirium, coma, and convulsions may also result. Id. Moreover, even in the absence of initial symptoms, symptoms such as peripheral neuropathy can manifest themselves sometime after the initial exposure, possibly resulting in peripheral nerve pain, tingling sensations, decreased sensation, and paralysis. Other delayed effects include depression of bone marrow, resulting in anemia. Id.

The treatment for arsenic poisonings includes induction of vomiting with syrup of ipecac, treatment by lavage (washing out the stomach with fluids), and administration of activated charcoal. Id. at 40-42.Treatment may also include chelation therapy with BAL (Dimercaprol) followed by oral treatment with penicillamine, another chelating agent, to aid in the elimination of arsenic from the body. Id. at 40.BAL therapy involves painful intramuscular injections and may be accompanied by serious side effects such as nausea, diarrhea, vomiting, pain and sterile abscesses at the injection site, mild shock, hypotension, tachycardia, anorexia, convulsions, and restlessness. Id.

The ALJ noted that there is disagreement among poison centers over the proper treatment for arsenic poisonings, particularly in asymptomatic cases. Id. One center recommends dilution of the poison with fluids and observation unless the patient ingested more than 5 ml of the bait or develops symptoms. Id. Another center recommends dilution and observation unless the amount ingested was greater than 2.5 ml. Id. at 41.If symptoms occur or the amount ingested exceeds 2.5 ml, vomiting is induced. Other centers proceed more cautiously. These recommend BAL treatment whenever symptoms appear or the patient is believed to have ingested at least 200 mg of sodium arsenate, and use oral chelation with penicillamine for asymptomatic patients with elevated arsenic levels in the urine more than one day after exposure. Id. While noting that this professional conflict need not be resolved in this proceeding (Id. at 51), the ALJ apparently accepted EPA's experts' opinions and concluded that early, aggressive treatment "is wholly justifiable" in view of the uncertainty surrounding the extent of toxic effects. Id. at 53.

Despite the wide range of serious symptoms that can result from arsenic poisoning, the evidence from poison control centers demonstrates that only about 10% of all exposures result in symptoms.

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For example, of the 1464 exposures to Terro or Jones in 1987 reported to AAPCC, 1161 showed no effect; 127 had a minor effect; 13 had a moderate effect; and none had a major effect. Id. at 34.[FN23] In the remainder of the cases (approximately 163), it is not clear what effect, if any, resulted. Of the cases involving children under six, 105 children suffered a minor effect and eight suffered a moderate effect. Id. at 49.It is estimated that the AAPCC data represent only about one-fourth of the total number of actual exposures. Id. Thus, the true number of symptomatic cases involving small children might be as high as 420 cases of minor effects, and 32 cases of moderate effects. Id. at 49-50.The ALJ found that these data by themselves presented cause for concern as to the risk. Id.; see also Id. at 38.Moreover, based on arsenic urine levels, the ALJ found that, of the 260 accidental exposures to sodium arsenate ant bait products reported to one regional poison control center, almost 94 (34.9%) were put at risk and required treatment. Id. at 38-40.The ALJ concluded that "[t]his number of incidents cannot be dismissed as insignificant or of only minimal concern."Id. at 40.

The ALJ analyzed the toxicity of sodium arsenate ant baits through the examination of animal data from laboratory tests, human exposure data furnished by poison control centers, and case studies of human exposures resulting in serious injury or death. From the animal data, the ALJ determined that the LD50 for the adult male hamster is 54 mg/kg, and that this datum is more reliable for estimating the risk to humans than the LD50 of 133 mg/kg obtained by Senoret in its rat study. Id. at 22.The judge cautioned, however, that animal data are somewhat crude estimates for assessing toxicity to humans. Consequently, the ALJ looked to the human data for additional support.

Patient studies involving fatal or near-fatal ingestions of Terro were used to arrive at a potentially lethal dose of sodium arsenate for a one-year old child. (All of the fatalities and near-fatalities were due to exposure to the contents of the bottle, not exposure to the bait station.) From this estimate, the judge concluded that if one accepts the rule of thumb that a significant illness may result from one-tenth the probable lethal dose, exposure to the bait station of any of the sodium arsenate ant baits could produce significant illness. Id. at 28-29.

The judge also looked at the risk to children from ingesting sodium arsenate from the product bottle. Doses received from ingesting an entire bottle all exceed the LD50 for sodium arsenate. Nevertheless, the ALJ concluded that the risk from drinking from the bottle itself is not a wide-spread risk. Id. at 49.The risk to a child coming into contact with sodium arsenate on the exterior surface of the bottle, however, is more serious. The ALJ cited the Blodgett Regional Poison Center data, which shows nine cases of bottle exposure. In two, the child drank from the bottle, and in the remainder the ALJ concluded that the child was at risk from coming into contact with the outside

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of the bottle. Id. at 48-49.Based on this information, the judge concluded that the risk of coming into contact with the sodium arsenate on the outside of the bottle does not occur very often, but should be considered along with the risk of the bait. Id. at 49.

The ALJ summarized his findings as follows:

> 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 creates a concern that there may be toxic effects unless prompt treatment is given. 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 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. ***.
>
> 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. ***[The evidence] 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. [FN24]

I accept these findings as summarized above (except as noted below) and, to the extent consistent with this decision, the ALJ's other risk findings set forth in his Initial Decision. Now I will turn to Senoret's exceptions to the ALJ's findings.

B. The Most Reliable LD50

Senoret takes exception to the ALJ's finding that the acute oral LD50 for the adult male hamster is more reliable for estimating the risk to humans than the LD50 obtained by Senoret for rats. [FN25] An acute oral LD50 is a statistically derived estimate of the single oral dose that would cause 50% mortality in the test population. [FN26] Thus, a higher LD50 indicates a lower toxicity. [FN27] EPA used the hamster based on a study by the National Academy of Sciences, which concluded that the rat was not a suitable test animal for determining the toxicity of arsenic to humans because the rat possesses a peculiar ability to bind arsenic in the hemoglobin of the red blood cells, thereby slowing down the release of arsenic to the tissue sites where it would be harmful. This %dy concluded that "the hamster appears [to be] the animal of choice" for arsenic toxicity studies. [FN28]

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Senoret contends that the National Academy of Sciences study is not relevant because it involved the use of trivalent, rather than pentavalent, arsenic. [FN29] The sodium arsenate found in the ant baits is pentavalent. [FN30] As noted by the ALJ, however, the National Academy of Sciences study recognized the differences between pentavalent and trivalent arsenic, and its recommendation to use hamster data is not limited to the latter. Initial Decision (pp. 20-21) (citing EPA Ex. 5 [pp. 120, 133-135]). The peculiar characteristics of arsenic metabolism in the rat appear to relate to arsenic in general, regardless of the valency. [FN31] For example, a report by the EPA Office of Research and Development found that sodium arsenate (pentavalent) was approximately 2.7 times more toxic to the hamster than to the rat. See EPA Ex. 6. Senoret has not provided any reason why the rat toxicity data should be considered more reliable than the hamster data. Nor has Senoret explained why the LD50 for the rat is 2.7 times higher than the LD50 for the hamster. In my view, Respondent has provided a sound justification, based on scientific evidence, for concluding that the hamster toxicity data are more reliable than that of the rat.

Other evidence presented by EPA provides further support for the use of the hamster data as an estimate of human toxicity. The estimates of toxicity from human case reports show that human death can result from doses of sodium arsenate in the range of 15 mg/kg to 89 mg/kg, [FN32] and studies done on rabbits and cats demonstrate minimal lethal doses of 51 mg/kg and 23 mg/kg, respectively. [FN33] These estimates suggest that the LD50 of 54 mg/kg in hamsters is probably a more accurate indicator of sodium arsenate toxicity and that reliance on the LD50 of 133 mg/kg for the rat is inappropriate. [FN34] Thus, I accept the ALJ's finding that the LD50 for the adult male hamster is more reliable for estimating the risk to humans than the LD50 obtained by Senoret in its rat study. [FN35]

Because I agree with the ALJ's finding that the hamster toxicity data is a more reliable indicator than the rat toxicity data, I must reject the remainder of Senoret's exceptions that rely on the rat data. For example, Senoret claims that, based on an LD50 of 5850 mg/kg for Terro, its product falls into EPA's category IV classification for toxicity, EPA's least toxic category. 40 CFR § 156.10(i)(D). When hamster data are used, however, Terro, with an LD50 of 2379 mg/kg, [FN36] falls well within category III, a more toxic category. [FN37]

Senoret also attempts to use a decision by EPA in 1974 to remove the word "poison" and the "skull and crossbones" from the Terro label as proof that Terro has a low toxicity, consistent with the rat data. Senoret argues that the ALJ failed to address this "earlier contradictory position on toxicity." Senoret's Exceptions (p. 47). EPA regulations do not require the word "poison" or the "skull and

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crossbones" to appear on a label unless the product falls into toxicity category I. 40 CFR § 156.10(i)(A). As discussed above, Terro falls within toxicity category III. A product need not fall into toxic category I to pose an unreasonable risk. Although Terro is not in the most toxic category, it is the combination of Terro's toxicity and the manner in which it is used—i.e., placed on open bait stations around the home in areas accessible to children—that creates the risk. [FN38]

C. The Risk Created From Exposure to a Bait Station

Senoret also takes exception to the ALJ's finding that the amount of Terro ingested from a bait station could result in a dose to a small child higher than the generally accepted margin of safety. The generally accepted practice in toxicity studies is to allow for a tenfold margin of safety—i.e., the probable lethal dose in humans should be considered to be ten times smaller than the probable lethal dose derived from animal studies. [FN39] The ALJ determined that if a small child (six months old, 7.4 kg) ingested the amount of Terro that could reasonably be expected to be on a bait station (2.5 ml), [FN40] the child would receive a dose of 9.22 mg/kg of sodium arsenate, a dose that substantially exceeds the one-tenth margin of safety (5.4 mg/kg) for sodium arsenate's LD50 of 54 mg/kg. Initial Decision at 23-25. [FN41]

Senoret's first objection to this finding is that exposed children suffered only minor illness. Yet as defined by the AAPCC (see note 23, supra), even so-called "minor" effects are not to be lightly ignored. For example, vomiting and diarrhea, although classified as "minor," can cause death from dehydration in small children if untreated. Tr. 485-486, 732. Moreover, the AAPCC data indicates that in 1987, of the reported cases of accidental exposure to sodium arsenate ant baits among children under six, eight cases showed a moderate effect. Because it is estimated that reports to participating poison centers account for only one-fourth of the actual number of poisonings, there may actually have been up to thirty-two cases showing moderate effects throughout the United States in 1987. [FN42] As noted above, these so-called "moderate" effects can be rather serious and can result in hospitalization. See note 23, supra. There are an estimated 276 emergency room visits each year resulting from sodium arsenate ant bait exposure. The medium age of emergency room cases is 12 months old. Fifty percent of these result in continued hospitalization. See EPA Exs. 1 (p. 44); 11.

Senoret does not deny that exposure to sodium arsenate ant baits has resulted in many symptomatic cases in children and that a large number of children are treated in medical facilities each year as a result of these exposures. Senoret appears to believe, however, that without large numbers of reported deaths or very serious illnesses caused by exposure to Terro bait stations, the product cannot be found to create an unreasonable risk. I disagree. The absence of reported deaths or very

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serious illness due to accidental exposure to a bait station does not mean there is not some risk of these events occurring. Moreover, as discussed above, the degree of risk warranting cancellation does not have to rise to any particular threshold. Any risk must be weighed and evaluated against the benefits of the product's continued use, provided it results from the use of the product in accordance with widespread and commonly recognized practice. See Section II.B., above. Here, the risk to small children results from the use of the baits in accordance with widespread and commonly recognized practice—i.e., placing open bait stations around the home wherever ants are seen. Thus, the risk of even minor or moderate illness is enough to warrant cancellation if it is not outweighed by the benefits of continued use.

Senoret's next objection is that the ALJ's risk analysis fails if any of his assumptions is changed. For example, Senoret asserts that if a child ingested only 1 ml [FN43] of Terro, the dose received would be 3.68 mg/kg, which is less than the one-tenth margin of safety. Likewise, if the child were larger than 7.4 kg, the dose received would be less than the margin of safety. The ALJ's finding, however, was not intended to imply that any child who ingested any dose of Terro would be at risk of significant illness. The ALJ's finding simply illustrates that an average six-month-old child ingesting an amount of Terro reasonably expected to be on a bait station would receive a dose large enough to put the child at risk of significant illness. Fifty-six percent of exposures to sodium arsenate ant baits involve children under one year old. EPA Ex. 1 (p. 30). A larger child consuming the same amount of bait may not be at risk of the same degree of significant illness, but would be at risk of some degree of illness, depending on the child's age, size, and general health.

Thus, I concur with the ALJ's finding that the amount of Terro that can reasonably be expected to be found on a bait station is enough to put a small child at a cognizable risk of significant illness. [FN44]

D. The Body's Ability to Detoxify Itself

Senoret next argues that exposures to Terro bait stations could not produce significant illness because of the body's ability to detoxify itself. Among the inorganic arsenicals, there is a large variation in the toxicity of various compounds. Pentavalent arsenic, such as sodium arsenate, is considerably less toxic to humans than trivalent arsenic, such as arsenic trioxide. [FN45] Senoret contends that, unless very large amounts of sodium arsenate are administered over a continuous period of time, it is rapidly eliminated from the body and very little accumulates in the tissue. Senoret's Exceptions at 61. Thus, Senoret maintains, small acute doses of sodium arsenate, such as the dose received from ingesting a bait station, cannot result in significant illness.

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I find no support for this argument in the record. While it is true that a large amount of sodium arsenate is excreted during the first 24 hours following an acute exposure, urine levels remain high for several days. Tr. 1093-95. The record shows that, once underreporting is factored in, each year there may well be as many as 452 symptomatic exposures (420 minor and 32 moderate) involving children under the age of six. [FN46] These numbers alone are enough to suggest that not all of the ingested sodium arsenate is rapidly excreted from the body; some amount of sodium arsenate must remain in the tissues, at least temporarily, where it exhibits its toxic effects. Senoret cites poison control center data, which show that out of the total number of exposures to sodium arsenate ant baits, only about 9% are symptomatic, and concludes that these data illustrate the body's ability to detoxify itself. Senoret fails to take into account, however, that there are many other possible explanations for the 91% asymptomatic cases. Notably, poison centers use the word "exposure" even in cases where there is no evidence that the child actually ingested the bait. See EPA Ex. 1 (pp. 12-13).[FN47] For instance, if a parent finds a child holding a bait station or even if the child is merely sitting near the bait station, the poison center would include the case in its total number of exposures. Naturally, symptoms would not be expected to occur if the child had never ingested any of the bait. Moreover, symptomatic cases may be underestimated because small children are not capable of verbally expressing the symptoms they may be experiencing. See EPA Ex. 1 (pp. 14-15) Tr. 479. Furthermore, the parent of a child who has just been exposed to an ant poison might be in a state of panic when telephoning the poison center, and thus might fail to perceive and report any symptoms. Generally the poison centers do not conduct thorough follow-up studies to determine whether there have been any cases in which delayed symptoms appeared. It also must be kept in mind that prompt treatment may prevent the onset or severity of symptoms. In any event, 452 symptomatic children per year is more than sufficient to conclude that sodium arsenate has some toxic effects on humans.

Moreover, scientific studies have shown that a certain percentage of pentavalent arsenic that is ingested will be converted in vivo to the trivalent form. Senoret Ex. 16 (p. 199); Tr. 1297. This conversion apparently takes place in the renal tubules of the kidney, where a portion of the newly formed trivalent arsenic is reabsorbed into the blood and carried back to the tissues to exert its toxic effects. Senoret Ex. 27 (pp. 2332-35). While there is controversy over the exact amount of conversion that takes place, it is apparently undisputed that the conversion occurs. Senoret cites a study on metabolism of sodium arsenate in dogs for the proposition that sodium arsenate is rapidly excreted with very little conversion to the trivalent form. Senoret Exs. 12A & 27; Tr. 1515-1516, 1519, 1602-1603, 1617. In my view, the dog study shows the exact opposite. Depending on the dose given (ranging from 0.73 mg/kg to 14.66 mg/kg of sodium arsenate) the dogs tested had urinary arsenite (a trivalent form of arsenic) levels from 8.9% to 23.2%. Senoret Ex. 27 (p. 2335).

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As demonstrated above, a small child exposed to a Terro bait station could receive a dose of approximately 9.22 mg/kg of sodium arsenate. Based on the dog conversion study, such a dose could result in a conversion of over 20% of the pentavalent sodium arsenate to the trivalent sodium arsenite (a form considered to be approximately four times as toxic as the pentavalent form). While I would agree with Senoret that much remains to be understood about the in vivo conversion of pentavalent arsenic to trivalent arsenic, the studies that have been done suggest that a significant amount of conversion takes place.

Thus, while the human body may have a certain capacity to detoxify itself, the evidence does not support Senoret's contention that this capacity eliminates the significant risk associated with exposure to sodium arsenate bait stations.

E. Delayed Adverse Effects

During the course of the hearing, EPA's expert witnesses described a number of potential delayed long-term adverse effects, or "sequelae," which could arise from acute poisoning with sodium arsenate ant baits. In the Initial Decision (p. 31), the ALJ outlined these sequelae. Senoret asserts that all of these delayed symptoms have been associated only with chronic ingestions of sodium arsenate and not with acute ingestions. Thus, Senoret contends, the ALJ's finding of a potential for delayed symptoms was unsupported by the record.

Senoret is correct that the record does not contain a reported case in which an acute accidental poisoning resulted in the later development of sequelae. [FN48] Given the state of knowledge on this issue, it is impossible to draw any firm conclusions regarding the risk of delayed sequelae from a single exposure to a bait station. Thus, I do not rely on the risk associated with the development of sequelae in making my determination that sodium arsenate ant baits pose a significant risk to human health. As explained more fully below in Section III.F., however, it is highly relevant to the risk analysis that many physicians are concerned about delayed or latent effects of arsenic ingestion and as a result administer unpleasant, and at times traumatic, treatment.

F. The Benefit of Prompt Treatment

The ALJ found that early appropriate treatment reduces the toxic effects of arsenic exposure. Because treatment itself can be so unpleasant, and to minimize the toxic effect of sodium arsenate generally, Senoret seeks to negate any suggestion that treatment is necessary (or even helpful) in reducing the toxic effects of sodium arsenate ingestion. Senoret relies on a study conducted by Drs. Kingston and Hall on cases reported to the Minnesota Regional Poison Control Center (MRPCC) to support its position. Senoret Exs. 69, 71 & 72. Of 149 cases of sodium arsenate ant bait expo-

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sures reported to the center for four and one half months in 1988, only four patients were symptomatic and were treated with syrup of ipecac. Id. From these data, Drs. Kingston and Hall concluded that MRPCC did not need to alter its existing protocol by recommending more aggressive treatment. See Senoret Ex. 74; Tr. 2391-2392.

Senoret argues that the Kingston and Hall study demonstrates that untreated patients did not exhibit any symptoms and that in light of the absence of symptoms in these patients, one cannot conclude that treatment prevents symptoms. Senoret's Exceptions (p. 67). To my mind, the only conclusion that can be drawn from this study is that out of the 149 patients, only a small number of them (i.e., four) exhibited symptoms. The patients' urine arsenic levels and the amount (if any) of bait ingested are not reported by Kingston and Hall. Without this information, it is impossible to use this study to disprove the ALJ's conclusion that early treatment reduces the toxic effects of arsenic exposure. That 145 asymptomatic patients in the Kingston and Hall study did not require treatment does not necessarily mean that treatment cannot reduce the toxic effects in other patients (i.e., patients who may have received a higher dose).[FN49]

Senoret contests EPA's assertion that chelation therapy can aid in the elimination of arsenic from the body. Senoret's Exceptions (p. 71). The theory behind the use of chelation therapy is that arsenic forms a molecular thiol arsenic complex with the chelating agent, thereby removing the arsenic from the tissues and enhancing its excretion from the body. See EPA Ex. 1 (pp. 34-35); Tr. 858-860, 888 & 1094. Senoret contends that because only a small amount of arsenic is absorbed by the tissue in cases of acute ingestion, chelation therapy is only effective in cases of chronic ingestion. Senoret's Exceptions (p. 72). As previously stated, Senoret has not shown that the amount of arsenic absorbed into the tissue in acute ingestions is so small as to be insignificant, and in any event, Senoret's assertions regarding chelation therapy simply are not supported by the record. In fact, the evidence in the record, including testimony of Senoret's as well as EPA's witnesses and medical literature, indicates that chelation therapy is most effective for acute ingestions, and less effective for chronic exposures. EPA Exs. 117, 134 & 184; Tr. 1902-1904. [FN50]

Moreover, the standard of care represented by Poisindex (the medical management information system used in all AAPCC Regional Poison Centers and in most other American poison centers) is the administration of chelation therapy for any symptomatic exposures. EPA Ex. 117 (pp. 46-49); Tr. 713-15. There is no reason to believe that Poisindex, which is derived from a consensus of opinion of poison experts throughout the United States and the world, would recommend a painful and risky form of treatment if it did not have some benefit in reducing morbidity from sodium arsenate poisoning. Chelation therapy causes pain and trauma, has serious side effects, [FN51] and

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can be very expensive. [FN52] It is not enough for Senoret to dispute the wisdom of this treatment; instead the risk associated with use of open sodium arsenate ant baits must be identified as it actually exists, including any risk to human health, physical or emotional, that might result from commonplace treatment techniques. The undisputed fact is that chelation therapy is a recommended practice in the treatment of arsenic poisonings. Tr. 1296. Finally, EPA presented several witnesses who testified that early appropriate treatment can reduce the toxic effects of sodium arsenate poisoning. In addition to these expert opinions, common sense suggests that removal of even some of the sodium arsenate from the stomach by inducing vomiting or lavage will result in less arsenic remaining in the stomach for later absorption into the blood stream, and subsequently into the tissues of the patient. [FN53] Senoret presents no evidence to contest this point. I accept the ALJ's finding that early and appropriate treatment may reduce the toxic effects of sodium arsenate poisoning. [FN54]

G. The Risk From the Outside of the Bottle

The ALJ found that, while the risk from exposure to the contents of the bottle was not widespread, exposure to product accumulated on the outside of the bottle posed a risk that must be taken into account in evaluating the overall risk from sodium arsenate ant baits. Initial Decision (p. 49). The ALJ based this finding on the Blodgett Regional Poison Center data, which indicated that during a seven and one half month period in 1988, there were nine cases reported where a child under six was exposed to a sodium arsenate ant bait bottle. Id. at 48.Because only two of these patients had high arsenic levels in their urine, the judge concluded that these were the only two children who may have drunk from the bottle. Id. at 49.As to the remaining seven children, the ALJ concluded 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."Id. Despite these findings favoring Senoret, the ALJ concluded that there is a cognizable risk from contact with the outside of the bottle that must be taken into account. Id.

I find insufficient support in the record for taking this alleged risk into account. From the Blodgett data, there is no way of knowing whether the seven children with lower arsenic urine levels drank small amounts from the bottle or only came in contact with the outside of the bottle. There was no record evidence that indicates the frequency with which children come into contact with the outside of the bottle or how much sodium arsenate ant syrup can reasonably be expected to be on the outside of the bottle. Moreover, the labels on the bottles of all of the ant baits at issue warn users to keep the product out of the reach of children. EPA Ex. 215 & Joint Stipulation. In contrast to the bait station, which is virtually impossible to keep out of the reach of children due to the manner of its use, the bottle can be easily stored in places inaccessible to children. There is no evidence in the

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record that there is a widespread or commonly recognized practice of leaving these bottles within the reach of small children. Thus, I find that there is no cognizable risk of children coming into contact with the outside of a sodium arsenate ant bait bottle.

H. Child-Resistant Bait Stations

Senoret asserts that it plans to place Terro in child-resistant bait stations on or before January 1, 1990, and that any potential risk will be addressed by this packaging. Although the Agency previously discussed child-resistant bait stations as an alternative short of cancellation, Senoret rejected this measure as unacceptable. See 53 Fed.Reg. 24794.Because Senoret has not yet developed this packaging, nor shown that it will meet EPA's standards for child-resistant packaging (or otherwise serve to eliminate the risk), nor shown that the product will be efficacious in such packaging, Senoret's future plans in this regard are irrelevant to this proceeding. Today's decision addresses only the existing registrations (and any pending applications) for sodium arsenate ant baits. Once Senoret has developed a child-resistant bait station, it may apply for a new FIFRA registration. [FN55]

I. Conclusions on Risks

Based on the record in this case, and for the reasons outlined above, I conclude that there is a risk of a significant number of symptomatic exposures to sodium arsenate from the widespread and commonly recognized practice of placing open bait stations of sodium arsenate baits around the home wherever ants are seen. The risk is primarily to children under the age of six, and the smaller the child, the more likely serious illness will occur. I do not accept Senoret's contention that there is no risk unless there is a risk of death or serious illness. See Senoret's Exceptions (p. 64). The risk of even minor illness is sufficient to invoke the risk/benefit balancing under FIFRA, provided the risk results from the use of the product in accordance with widespread and commonly recognized practice. Moreover, even so-called "minor" or "moderate" effects can have serious consequences in small children if not properly treated. Respondent has also shown that one recommended treatment, chelation therapy, is very traumatic and painful and can cause serious side effects. Such treatment is administered to more than 40 persons per year due to exposure to sodium arsenate ant baits.

IV. THE BENEFITS OF CONTINUED USE

In analyzing the benefits of continued use of sodium arsenate ant baits, the ALJ examined three core issues: the relative efficacy of such baits and alternative bait formulations; the relative risk posed by these products; and the economic effect of cancellation. Finding that the alternative baits

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are equally effective, no more dangerous, and comparably priced, the ALJ concluded that cancellation of sodium arsenate baits would have no adverse economic consequences and that the risk of their continued use outweighs the benefits. I am adopting the ALJ's ultimate findings on the benefits issue, but, as explained below, my reasoning differs in certain respects. As with the risk analysis in Section III, for continuity I will briefly summarize the ALJ's findings on the benefits issue and then address the specific exceptions raised by Senoret.

A. The ALJ's Findings

Judge Harwood began his benefits analysis by finding that sodium arsenate ant baits are effective for the control of small populations of sweet-eating ants. Initial Decision at 54-63. [FN56] Relying on expert testimony, an assessment by the U.S. Department of Agriculture, and consumer acceptance of these products, the ALJ rejected Respondent's position that there is no valid proof that sodium arsenate baits are effective. Id. Yet he stopped short of finding that these products are the most effective ant baits for the control sweet-eating ants. Id. The ALJ then evaluated the numerous alternative ant baits registered under FIFRA, finding that these alternatives are "not totally ineffective." Id. at 66.[FN57] Despite this rather qualified finding of efficacy for the alternatives, the ALJ nevertheless determined that sodium arsenate baits and the alternative baits are of comparable efficacy, stating that the efficacy studies for all ant baits contain limitations and deficiencies and that the most that could be said about any ant bait is that it is "not totally ineffective." Id. at 66-67.The ALJ also noted that no state cooperative extension service has ever found sodium arsenate ant baits to be more effective than other ant bait products. Id. at 69-70.

Turning to the relative risk posed by sodium arsenate baits and alternative baits, the ALJ found that Senoret failed to prove its contention that the alternatives are more dangerous. Id. at 73-74.He determined that the active ingredients in the alternatives are "considerably less toxic" than sodium arsenate. Id. at 71.Although some alternatives might also contain toxic inert ingredients, the ALJ noted that the alternatives are nevertheless safe enough to be registered. He also concluded that Senoret could not meet its burden of persuasion on the relative toxicity issue simply by citing human exposure incident figures for active ingredients contained in the alternatives, particularly because these data fail to indicate whether the exposures involved ant baits (as opposed to other kinds of products). In contrast to the extensive record evidence relating to the risk of sodium arsenate ant baits, the ALJ found the record devoid of public information suggesting that the alternative baits pose any significant risk. Id. at 73.

The ALJ next evaluated the economic ramifications of cancellation, concluding that the impact would be insignificant. The ALJ found that the ant bait market is elastic and that cancellation

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would not cause a significant increase in the price of the alternatives because: (1) substitute baits are comparably priced; (2) the leading companies producing the alternatives are larger than the producers of sodium arsenate ant baits; and (3) the ant bait market makes up only a small fraction of the total home insecticide market. Id. at 74-79.The ALJ rejected Senoret's argument that cancellation would result in consumers turning to costly professional pest control operators, finding this argument unpersuasive "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."Id. at 79.Thus, the ALJ concluded that consumers will suffer no adverse economic consequences as a result of cancelling the registrations for the sodium arsenate ant bait products. Id.

I accept the ALJ's benefit findings as summarized above and as supplemented and modified below. I now turn to Senoret's specific exceptions.

B. Due Process

Senoret's primary argument on Appeal is that it was denied due process because Respondent refused to disclose certain confidential business information (CBI) relied on by Respondent's expert witnesses in preparing their testimony. The undisclosed CBI was submitted to the Agency under FIFRA by the registrants of the alternative ant baits, and must be treated as confidential by virtue of FIFRA § 10(b).[FN58] The CBI relates to the product formulations and the market shares of the alternative ant baits, and thus Senoret's due process challenge cuts across all three core benefit issues (relative efficacy, relative risk, and the economic effect of cancellation).[FN59] Senoret argues that the ALJ deprived it of an opportunity for effective cross-examination of Respondent's experts by refusing to compel in camera disclosure of the CBI. Senoret's Exceptions (p. 6). It requests a remand with instructions to compel such disclosure or, alternatively, that the ALJ's benefit findings be rejected.

Although Senoret cites several federal court decisions to support its argument (Senoret's Exceptions at 10-11), each of these cases involves an agency's reliance on undisclosed confidential information. [FN60] Here, the ALJ expressly stated that he did not rely on testimony based on CBI. Initial Decision (p. 67-68). I am likewise disregarding all testimony based on undisclosed CBI in making my findings today. As discussed in more detail below, the record nevertheless shows that there are numerous effective, safe, and comparably priced alternatives available for ant control. In other words, even without the testimony based on undisclosed CBI, Respondent has presented a prime facie case for cancellation, and Senoret has failed to meet its burden of persuasion that the benefits of sodium arsenate ant baits outweigh the risks. Thus, Senoret has not been prejudiced by the undisclosed CBI and its due process argument is rejected. [FN61]

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C. The Relative Efficacy of Ant Control Alternatives

As noted above, the ALJ found that sodium arsenate ant baits and alternative baits are comparably effective for the control of small infestations of sweet-eating ants, stating that the most that can be said of either category is that the products are "not totally ineffective." Initial Decision at 66-67. Senoret argues that alleged design flaws in the efficacy studies for the alternatives undermine the ALJ's finding that they are as effective as sodium arsenate baits.

In analyzing this argument, it is important to note that under FIFRA § 3(f)(2), registration of a pesticide constitutes prima facie evidence of compliance with the Act, including compliance with claims of efficacy, unless cancellation proceedings are in effect. Because Respondent established that more than forty registered alternatives exist, the rebuttable presumption created by FIFRA § 3(f)(2) shifts the burden to Senoret to demonstrate by a preponderance of the evidence that the alternatives are ineffective or unavailable. [FN62]

Senoret attempts to rebut the presumption of efficacy for the numerous registered alternative ant baits by criticizing the underlying efficacy field studies as having design deficiencies. Senoret's Exceptions (pp. 23-34). Senoret's criticisms are unfounded. For example, Senoret argues that the field studies conducted on many alternatives were not designed to test for a delayed toxicant effect, i.e., a toxicant which does not exert its effect until after the worker ant has returned to the nest and fed the bait to other members of the colony. Yet Respondent's expert, Mr. Brassard, made clear that field studies are generally conducted *after* a delayed toxicant effect has already been demonstrated in laboratory screening tests. Tr. 3367, 3376. [FN63] Another alleged shortcoming of the alternative field studies, the lack of posttreatment mortality counts, is simply due to the nature of actual-use testing. If a test is conducted on an ant nest in the wall of an apartment building, for example, it is unreasonable to expect the tester to tear down the wall at the end of the study to count the number of dead ants in the colony. *See, e.g.* Tr. 3141, 3359, 3382. Although Senoret argues that many outdoor efficacy studies are not useful, EPA explained that the Agency typically accepts outdoor studies as reliable due to the difficulties involved with indoor studies (*e.g.*, building tenants destroying data).*See* EPA Exs. 225 (p. 18); 228.

Although Respondent's expert failed to address some of Senoret's study design criticisms--such as the lack of control groups and pretreatment counts in some test--it is highly significant that Senoret itself has not presented *any* conclusive efficacy study on it Terro product. The only existing study on Terro is a preliminary lab study conducted by Senoret's expert, Dr. Traniello, which he described as only the first level of analysis of a delayed action toxicant. Senoret Ex. 90 (p. 2). The

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study does suggest that Terro may be a delayed action toxicant under certain circumstances, but without an actual-use field study, it is impossible to compare Terro's effectiveness with that of the alternative baits.*See* Senoret Ex. 90 (p. 2). Another study conducted on the Jones product was so poorly designed that, in my view, it has very little (if any) significance. [FN64] Thus, despite the limitations of the efficacy studies on the alternative baits, several of these studies are more meaningful than existing study on sodium arsenate ant baits.

Perhaps the most telling evidence on the relative efficacy of the ant baits was presented by Dr. Traniello himself. He frankly admitted that many alternative baits are effective against several ant species. Senoret Ex. 88. He explained that the diversity of house-infesting ants and their wide range of feeding habits makes it unlikely that any particular formulations would be effective in all situations. See Senoret Ex. 86. Dr. Traniello's primary criticism of certain field studies was that they showed only ant mortality, not delayed toxicant effects. See Senoret Ex. 86 (pp. 6-7). But significantly, Dr. Traniello conceded that "[b]asically the same problems [i.e., the lack of conclusive efficacy studies] exist for arsenical toxicants."Senoret Ex. 86 (p. 7). This testimony strongly supports the ALJ's finding that, in view of the inconclusive nature of existing efficacy studies on all ant baits, Senoret has failed to show that sodium arsenate baits are superior. [FN65]

Senoret also contends that EPA's refusal to release CBI regarding inert ingredients for the alternative baits makes it impossible to determine whether the alternative baits contain sucrose or other ingredients that attract sweet-eating ants and thus whether they are effective against such ants. The record shows, however, that for at least five of the more common alternative baits, either an efficacy study has been done on the entire formulation (including the inert ingredients) or the inert ingredients are known. [FN66] Moreover, one of the alternative borax ant baits, Terro California Ant Killer, is manufactured by Senoret. Senoret is certainly aware of the inert ingredients in its own product, and not surprisingly, it offered no evidence to show that this product is ineffective. [FN67] Furthermore, Senoret could have conducted its own testing to determine whether the alternative baits contain sugar or other inert ingredients that attract sweet-eating ants. While I am not relying on testimony based on undisclosed CBI, in my view the Agency is not obliged to disclose CBI for proposed alternatives in a cancellation proceeding, especially where the Petitioner may obtain the relevant information elsewhere. [FN68]

Finally, in determining whether there are effective alternatives to sodium arsenate ant baits, it must be observed that literally thousands of non-bait products are registered for ant control. [FN69] Although the parties have focused on bait alternatives, ant control experts, research entomologists, and pest control operators recommend location and treatment of the nest with residual insecticides

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(such as aerosol sprays and dusts) as the preferred method of control for most species of household pest ants. EPA Exs. 219 (pp. 476-77); 230 (p. 134); 231 (p. 32); 274; Tr. 2738-40. Where nest location is difficult, other recommended techniques include the treatment of ant travel paths and entry points, again with residual insecticides. [FN70] Due to their FIFRA registrations, these non-bait alternatives are presumed to be effective, and Senoret has offered no evidence to rebut this presumption. There are, of course, certain advantages to baits, particularly those with a delayed toxicant effect, and undoubtedly there are consumers who prefer bait to non-bait products for ant control in certain situations. Nevertheless, in the absence of sodium arsenate ant baits, many consumers would presumably turn to the thousands of effective non-bait products.

In sum, I find that there are numerous bait and non-bait alternatives that are equally effective against sweet-eating ants. Senoret has not met its burden of rebutting, by the preponderance of the evidence, the statutory presumption that the alternative products registered for use on ants are effective.

D. The Relative Risk Posed by the Alternatives

The ALJ found that cancellation would not likely result in any increased safety hazard because the alternatives do not pose a greater risk to human health than the sodium arsenate ant baits. Senoret disagrees, and argues that in order to reach this conclusion, the ALJ must have relied on undisclosed CBI regarding alternative bait formulations (despite his assertion to the contrary). Senoret thus renews its argument that it was prejudiced by Respondent's failure to make this CBI available. Senoret's Exceptions (pp. 7, 15).

To put this argument into context, it is necessary to review the testimony of Respondent's witness on this issue, Jerome Blondell, who testified that the alternative baits are less toxic than the sodium arsenate baits. He presented data showing that the LD50s of the active ingredients in the alternative baits are considerably higher (i.e., less toxic) than the LD50 for sodium arsenate. EPA Rebuttal Ex. 1 (p. 5-6); Tr. 364-3665. Senoret's position is that a bait's inert ingredients must also be examined to evaluate its overall toxicity, and it therefore attempted to elicit from Mr. Blondell the inert ingredients of the alternative baits. Mr. Blondell responded that he could not disclose the inert ingredients because this information is CBI protected from disclosure under FIFRA § 10. He did testify, however, that he examined the CBI for each alternative bait and concluded that the inert ingredients were primarily food substances that would not add to the toxicity of the alternatives. Id.

In the Initial Decision, the ALJ expressly stated that he gave no weight to the portion of Mr. Blondell's testimony regarding the make-up or toxicity of the inert ingredients because Senoret

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was deprived of effective cross-examination on that issue. Initial Decision (p. 72). Notwithstanding Senoret's suggestion to the contrary, there is nothing before me to suggest that the ALJ departed from this self-imposed restriction. More importantly, my findings below are derived entirely from the portions of the record that were not based on CBI. Thus, as noted in Section IV.A, Senoret was not prejudiced by Respondent's refusal to disclose this CBI.

Excluding the testimony based on the CBI for inert ingredients in the alternative baits, the record still shows that the ant control alternatives do not pose a greater risk to human health than do the sodium arsenate baits. The most compelling evidence on this issue is that many of the alternative baits are not used in a manner likely to result in exposures. For example, the PIC Ant Trap, the Black Flag Ant Control System, and the Combat Ant Control System all come in child-resistant baits stations. See EPA Exs. 217, 214-B & 214-D. Several other alternatives come in metal ant traps, including the Raid Ant Controller, the Ortho Ant Killer Bait Station, the TAT Ant Trap, and the Grants Ant Control Stakes. See EPA Ex. 217. Although these traps have not been demonstrated to meet EPA's regulatory child-resistance standards, they apparently do help to protect children, for there is no evidence in the record that these traps have resulted in any exposures. In contrast to the open bait stations used for sodium arsenate—such as pieces of cardboard, crackers, bread, bottle caps, and open cups—all of the above alternatives, by their very nature, are less likely to be sources of exposure to children, regardless of their inert ingredients. Moreover, there is no record evidence to suggest that the thousands of registered non-bait alternatives for ant control pose any risk at all.

Senoret, not EPA, has the burden of demonstrating that the alternatives are more toxic than the sodium arsenate baits. In re: Velsicol Chemical Co., et al., 41 Fed.Reg. 7552, 7554 (February 19, 1976); In re Stevens Industries, Inc., 37 Fed.Reg. 13369, 133727 (June 14, 1972). Although Senoret argues that it is impossible for it to meet its burden without access to the CBI regarding the inert ingredients of the alternative baits, Senoret had several options. For example, Senoret could have attempted to obtain information on inert ingredients from other registrants, or analyzed the alternative products itself to determine the identity of their inert ingredients or the toxicity of the product as a whole, or used reports from poison control centers or other medical literature to show the number of poisonings that have occurred from any or all of the alternatives. Senoret took none of these steps. Nor did it attempt to compel disclosure of the identity of the inerts in a timely fashion prior to trial. See note 68, supra. Because Mr. Blondell's testimony based on undisclosed CBI has been disregarded, Senoret stands in no different position from any other petitioner in a cancellation proceeding and cannot claim prejudice due to the ALJ's refusal to order in camera disclosure.

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Thus, I accept the ALJ's finding that the available alternative ant baits do not pose a higher risk to human health than do the sodium arsenate ant baits, and I find independently that there is no evidence to suggest that non-bait products pose a greater risk.

E. The Economic Impact of Cancellation

The ALJ found that cancellation would not result in a significant economic impact. Senoret again argues that it was prejudiced by EPA's refusal to disclose CBI regarding the market share of the alternative ant bait products, thereby effectively depriving it of an opportunity to cross-examine Respondent's economic expert, Mr. Dumas, [FN71] on his calculations based on this information. [FN72] Senoret's Exceptions (p. 38). I disagree. The ALJ expressly stated that he did not rely on any of Mr. Dumas' testimony that was based on undisclosed confidential information. After a careful evaluation of the record, and disregarding all evidence based on confidential information, I too find that cancellation of sodium arsenate ant bait products will not have a significant economic impact.

Mr. Dumas established four key points. First, he testified that there are numerous bait alternatives available at prices comparable to that of the sodium arsenate baits. Based on an informal telephone survey of stores that sell insecticides, Mr. Dumas determined that several alternative baits are available in the price range of $1.39 to $2.59. EPA Ex. 214 (Tables 2 & 3). The price of Terro is between $1.79 to $2.29. Id. While this survey is admittedly informal, Senoret has not presented any evidence to dispute its results.

Second, Mr. Dumas explained that, apart from individual market shares, the sheer number of available alternative ant baits (i.e., more than 48 total registered ant baits) provides some indication that the market is elastic, and thus that cancellation of one type of bait will not result in significant price increases in the other bait products. EPA Ex. 214. Senoret offers no evidence to dispute this.

Third, Mr. Dumas provided evidence that some of the manufacturers of the alternative baits are the largest pesticide manufacturers in the country. See EPA Ex. 307 (Table 2-18). Thus, these large companies would likely be able to increase production to meet any increase in demand created by the cancellation. The leading companies producing the alternative baits are larger than any of the current producers of sodium arsenate baits. See Id.Although Senoret argues that any conclusion regarding other producers' ability to meet increased demand must of necessity be based on undisclosed CBI regarding market share, the key factor in filling any gap in the market is not existing

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market shares, but barriers to entry into the newly opened markets. In Mr. Dumas' expert opinion, the huge size of the alternative bait producers and the availability of sufficient amounts of alternative active ingredients (as well as the sheer number of alternative baits mentioned above) will be more than sufficient to overcome any such barriers. See EPA Ex. 214. Because Senoret failed to sponsor an economist as a witness, this testimony stands undisputed on the record and in my view is entitled to significant weight.

Fourth, Mr. Dumas testified, based on his expertise as an economist, that sodium arsenate ant baits constitute a very small portion of the total ant control market. Id. One basis for this statement is that he could not find any information regarding the market share of sodium arsenate ant baits in the public literature or in EPA's extensive files on pesticide usage. See Id. at 5-6.[FN73] This testimony confirms my earlier finding that, upon cancellation, many former users of sodium arsenate ant baits would turn to the thousands of non-bait products available for ant control.

Senoret's main argument regarding the economic impact of cancellation is that consumers will be forced to hire costly professional pest control operators if the registrations for sodium arsenate ant baits are cancelled. Senoret's Exceptions (p. 36). This argument assumes that there are not effective alternative baits available to replace the sodium arsenate baits. As discussed above, however, the record demonstrates that numerous effective alternatives are available.

Assuming arguendo that there are no effective alternatives, Senoret's argument still fails. Senoret asserts that 86% of the homeowners surveyed by the University of Nebraska hired pest control operators after their own efforts at extermination had failed. Senoret's Exceptions (p. 36); EPA Ex. 310. This assertion is a serious distortion of the record. In fact, the survey indicates that only 3 or 4% (depending on the year) hired pest control operators after their own efforts failed, and that of these 3 or 4%, 86% were homeowners (as opposed to apartment or mobile home dwellers.) Id. at 8, 14.Of the approximately 1.2 million users [FN74] of sodium arsenate ant baits annually, at most 48,000 (1.2 million x 4%) would switch to professionals absent an effective, cheaper alternative. Treatment by a professional costs $25 to $75, depending on the size of the structure and the part of the country in which the structure is located. See Tr. 3849. Thus, assuming the absence of effective alternatives, cancellation of sodium arsenate ant baits would result in increased costs for professional pest control of about $2.4 million annually (48,000 x a mid-range cost figure of $50). Subtracting the $2.4 million currently spent for sodium arsenate baits (1.2 million bottles x a mid-range cost of $2 per bottle), the overall net cost to consumers is zero. Thus, even assuming that no effective alternatives are available, cancellation would have no adverse economic effect on consumers as a whole because the overwhelming majority (96-97%) would simply tolerate the

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ants. [FN75]

V. CONCLUSIONS: THE RISK-BENEFIT BALANCE

A review of the record evidence, the Initial Decision, and the parties' post-trial and appellate submissions demonstrates that Respondent presented a prima facie case for cancellation due to the large number of exposures to sodium arsenate ant baits each year, and that Senoret has failed to meet its burden of showing that the benefits of continued use justify the risks. The manner in which these baits are packaged and actually used makes it virtually impossible, despite the label warnings, to keep them out of the reach of children. While most of the reported exposures are not symptomatic, there are up to 452 cases each year (depending on how one accounts for underreporting) in which a child suffers some illness from exposure to these baits. Although these illnesses are classified as "minor" or "moderate," they cannot be blithely ignored. Even so-called minor symptoms, such as nausea or diarrhea, can be serious in a small child, particularly if the child does not receive the proper medical attention. Respondent has also provided data from animal tests and medical case studies, indicating that even small doses of sodium arsenate can be toxic to small children, and thus put small children at risk of significant illness. Moreover, Respondent has shown that one recommended treatment for sodium arsenate poisoning, chelation therapy, is very traumatic and painful, and can cause serious side effects. Such treatment is administered to more than forty persons annually due to exposure to sodium arsenate ant baits.

On the benefits side of the balance required by FIFRA, it must be kept in mind that the sodium arsenate ant baits at issue are used solely to control very minor infestations of nuisance ants. These baits are not useful against infestations that pose a threat to human health, food crops, or the structural integrity of buildings. At worst, cancellation of these products will result in consumers tolerating the presence of a small number of ants—a small price to pay to protect the health of hundreds of small children each year. Due to the availability of a large number of comparably priced alternative ant baits, as well as many non-bait ant control insecticides and techniques, it is highly unlikely that this worst case scenario would occur. Senoret has not met its burden of showing by a preponderance of the evidence that the comparably priced alternative means of ant control are unavailable or ineffective.

As required by FIFRA § 19, I have considered the proper disposition of existing sodium arsenate ant bait stocks. The June 30, 1988 Notice of Intent to Cancel stated that the Agency has determined that sale and use of existing stocks of inorganic arsenical products is inconsistent with FIFRA and will cause unreasonable adverse effects on the environment. The Notice stated that allowing the

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sale and use of existing stocks would not be prudent and would put additional children at risk. 53 Fed.Reg. 24794.Senoret has not met its burden of showing that it should be permitted to sell existing stocks and there is nothing in the record to suggest that anything other than immediate cancellation is appropriate. Terro has a long shelf life and thus, if I were to permit the continued sale of existing stocks, additional children would be put at unreasonable risk for years to come. See Tr. 1816. Thus, all existing stocks are subject to the final order prohibiting their continued sale, distribution, or use. [FN76]

FINAL ORDER

1. The registrations for sodium arsenate ant baits at issue in this proceeding are cancelled, and pending applications for such baits are denied.

2. For purposes of this Order, "existing stocks" are defined as any quantity of sodium arsenate ant bait products subject to this Order that has been formulated, packaged and labeled for use and is being held for shipment or release or has been shipped or released into commerce prior to the effective date of this Final Order.

3. The sale, distribution, and use of existing stocks of the sodium arsenate ant bait products at issue in this proceeding are prohibited.

4. This Order shall become effective at the date and time it is filed with the hearing clerk.

FN1 As the Administrator's delegatee, I have authority to decide FIFRA cancellation Appeals. 40 CFR § 164.2(d) & (k). Although the entire record was taken into account in making this determination, record citations are illustrative, not comprehensive. I have adopted the record citation format used by the Presiding Officer. See Initial Decision at 4, note 8. The parties' briefs on Appeal are cited as "Senoret's Exceptions" and "EPA's Reply." The parties' post-trial briefs to the Presiding Officer are cited as "[EPA/Senoret] Tr. Bf." and "[EPA/Senoret] Tr. Reply." Senoret's Proposed Findings of Fact and Conclusions of Law are cited as "Senoret's Proposed Findings."

FN2 No determination has been made as to whether the child resistant cap complies with EPA's standards for child-resistant packaging set forth in 40 CFR § 157.22. Initial Decision (p. 47, note 136).

FN3 The chemical formulation of the sodium arsenate found in Terro is known as "dibasic sodium

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arsenate," the specifications of which are: SODIUM ARSENATE (Arsenic acid, disodium salt; CAS 7778-43-0; Molecular formula As-H-04 .2Na; Molecular Weight 185.91). See EPA Ex. 117 (p. 20); EPA Ex. 171.

FN4 The chemical formulation for the sodium arsenate found in the Jones product is not specified in the record.

FN5 The specifications of the chemical formulation of the sodium arsenate found in FATSCO are: SODIUM ARSENATE (Arsenic acid, sodium salt; CAS 7361-89-2; Molecular Formula As-H3-Ox .xNA; Molecular Weight 302.88). See EPA Ex. 117 (p. 20).

FN6 The chemical formulation for the sodium arsenate found in the Protexall product is not specified in the record.

FN7 On January 10, 1986, the Agency issued an Amended Notice of Intent to Cancel (51 Fed.Reg. 1334), which applied only to wood preservative uses of arsenicals. Either the registrants of wood preservative arsenicals have modified their registrations in accordance with the requirements of this Amended Notice, or their registrations have been cancelled by operation of law. See 53 Fed.Reg. 24788.

FN8 The Preliminary Determination did not apply to "major uses" of inorganic arsenicals, such as the turf herbicidal use of the flowable formulation of calcium arsenate, the grapefruit growth regulator use of lead arsenate, the grape fungicidal use of sodium arsenite and the desiccant uses of arsenic acid. These uses are still under Special Review.

FN952 Fed.Reg. 132.

FN10 For sodium arsenate ant baits, the Preliminary Determination listed diazinon, chlorpyrifos, and propoxur as comparably priced alternatives. 52 Fed.Reg. 138.

FN11 The U.S. Department of Agriculture did not have any objection to the cancellation proposal. 53 Fed.Reg. 24791.

FN12 The Scientific Advisory Panel waived review and comment on the Notice of Preliminary Determination. 53 Fed.Reg. 24791.

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FN13 Like the Preliminary Determination (see note 8, supra), the Notice excepted the major uses of inorganic arsenicals from cancellation because they are still under Special Review. The notice also excepted registrations for the solid formulations of arsenic trioxide used to control ants, moles, gophers, and pocket gophers. 53 Fed.Reg. 24787.

FN14 All registrations for insecticide baits containing sodium arsenite and lead arsenate have been voluntarily cancelled.

FN1553 Fed.Reg. 24792.

FN1653 Fed.Reg. 24794.

FN17 Jones Products, Inc. was the only inactive party to submit a post-trial brief. See Post-Hearing Brief of Jones Products, Inc. (April 11, 1989). A fifth company, General Pest Service, Co., was a registrant of a product containing arsenic trioxide, which was also used to control ants. On November 23, 1988, General Pest Service withdrew its objections. Thus, the only registrants remaining for the hearing were the four registrants of sodium arsenate ant baits.

FN18 In its exceptions, Senoret requests an opportunity to present oral argument before the Administrator pursuant to 40 CFR § 164.101(c). This request is denied.

FN19 Although Respondent prevailed at the trial level, it filed exceptions to a May 22, 1988 evidentiary ruling excluding written summaries of telephone conversations prepared by one of Respondent's experts. This issue is discussed in note 76, below.

FN20 The labels for the sodium arsenate ant baits appear to be internally inconsistent. The labels direct users to keep the products out of the reach of children and to place the bait stations around the home wherever ants are seen. Apparently, it is virtually impossible to do both. See note 38, infra.

FN21 As the ALJ pointed out in the Initial Decision (p. 50, note 147), isolated instances of negligent or intentional misuse of the product would not demonstrate a risk resulting from the use of the product in accordance with widespread and commonly recognized practice.

FN22 To be effective, ant bait stations must be placed where ants are present. Such locations are often accessible to small children. See note 38, infra.

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FN23 The AAPCC defines a medical outcome as a "minor effect" when a patient exhibits some symptoms but they are minor or no treatment was provided. Examples of minor symptoms are: mild gastrointestinal symptoms such as vomiting and diarrhea, drowsiness, skin irritation or primary, burn, and sinus tachycardia without hypotension. EPA Ex. 134 (p. 4).

The AAPCC defines "moderate effect" as symptoms that are more pronounced, more prolonged or more of a systematic nature than minor symptoms. Usually some form of treatment is indicated. Examples of moderate symptoms are: high fever, hypotension, isolated brief seizures, transient renal failure not requiring dialysis, hepatic injury without encephalopathy, and gastrointestinal symptoms causing dehydration EPA Ex. 134 (p. 4).

The AAPCC defines "major effect" as symptoms that are life-threatening or result in residual disability or disfigurement. Examples include patients who require intubation plus mechanical ventilation, who sustain repeated seizures, or experience ventricular tachycardia, cardiovascular instability or coma. EPA Ex. 134 (p. 4).

FN24 Initial Decision at 52-53 (footnotes omitted).

FN25 Senoret argues that EPA testing guidelines, 40 CFR § 798.1175, indicate that the preferred test animal for LD50 studies is the rat. These guidelines were issued under the Toxic Substances Control Act, 15 U.S.C. § 2601 et seq., not FIFRA. In any event, these guidelines allow the use of other animals as long as the tester provides justification and reasoning for its selection. 40 CFR § 798.1175(f)(1)(i). Here, EPA clearly provided justification for using test animals other than rats.

FN26 See 40 CFR § 152.3(e).

FN27 Senoret also objects altogether to the use of animal studies to determine the toxicity of sodium arsenate in humans. Although human case data are generally better predictors of the toxicity of a poisonous substance, it is well settled that animal data may also be useful predictors. See EDF v. EPA, 598 F.2d 62, 87 (D.C.Cir.1978) ("It is well established that evidence concerning toxic effects on mammals is probative of dangers to man."); see also EDF v. EPA, 510 F.2d 1292, 1299 (D.C.Cir.1975). In fact, EPA requires a large number of animal tests as part of the data required for registration of a pesticide under FIFRA. See 40 CFR Part 158.

FN28 EPA Ex. 5 (p. 110).

FN29 A trivalent molecule has the capacity to form three bonds with other atoms; a pentavalent

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molecule has the capacity to form five bonds with other atoms.

FN30 Scientific experts agree that the trivalent form of arsenic (for example, the form of arsenic in arsenic trioxide) is considerably (approximately four times) more toxic than the pentavalent form. See EPA Exs. 5, 137, 192 & 196; Senoret Exs. 12 & 21; Tr. 74, 716, 896, 933 & 947.

FN31 EPA witness Dr. Hutton testified that the only difference between trivalent and pentavalent arsenic poisoning is quantitative, not qualitative. Tr. 547-550.

FN32 The three human case reports used were: a 57-year-old female who died from a dose of sodium arsenate estimated to be 29 mg/kg; a five-year-old female who died from a dose of sodium arsenate estimated to be in the range of 15-89 mg/kg; and a 32-year-old man who received a dose of sodium arsenate of 51 mg/kg and probably would have died without prompt treatment. See EPA Exs. 1 (pp. 38-39, 41-42), 7 (pp. 17-19, 23-24), 186; EPA Rebuttal Ex. 1 (pp. 1-5, 9); Tr. 326-329, 1254-55.

FN33 See EPA Exs. 117 (p. 20) and 20.

FN34 Senoret's study showed an LD50 of 5850 mg/kg for the Terro product in the adult female rat, which translates to 133 mg/kg for sodium arsenate (5850 mg/kg x 2.27% (concentration of sodium arsenate in Terro) = 133 mg/kg). See Senoret Ex. 75.

Senoret also contests Respondent's determination of a minimal lethal dose of 30 mg/kg in hamsters. Senoret argues that a dose of 30 mg/kg was never administered to even one hamster. Senoret is wide of the mark. In the hamster study, a dose of 50 mg/kg of sodium arsenate heptahydrate was administered to 10 young and 10 adult hamsters. In each group, one individual died. Fifty mg/kg of the heptahydrate translates to approximately 30 mg/kg (to be precise, 29.8 mg/kg) of sodium arsenate. See EPA Ex. 6.

FN35 Senoret has also criticized EPA's LD50, test on hamsters because the study was conducted with sodium arsenate heptahydrate. Senoret, however, has not provided any evidence or rationale to suggest that the use of the heptahydrate would alter the toxicity. In the heptahydrate compound, seven water molecules are bound to the sodium arsenate. EPA took this into account when it calculated the LD50 for hamsters. The test on the heptahydrate showed an LD50 of 91 mg/kg. This figure was multiplied by 0.596 (a mathematical adjustment to exclude the molecular weight of the heptahydrate) to obtain the LD50 of 54 mg/kg for sodium arsenate. See EPA Ex. 1 (p. 18). It is also to be noted that EPA's toxicity study on rats conducted with sodium arsenate heptahydrate showed

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an LD50 of 144 mg/kg. Senoret's study on rats using sodium arsenate (not the heptahydrate) showed an LD50 of 133 mg/kg. I agree with Judge Harwood that Senoret has not shown these figures to be materially different. Initial Decision at 21. Even if this were a meaningful difference, it appears that the heptahydrate is less toxic (the higher the LD50, the lower the toxicity) in which case EPA's estimates of the LD50 of sodium arsenate in hamsters might be too high, not too low as Senoret suggests.

FN36 The LD50 for the Terro product was determined by dividing 54 (the LD50 for sodium arsenate in hamsters) by 2.27% (the concentration of sodium arsenate in Terro). The LD50s for the other ant bait products, similarly calculated are: Jones—3600 mg/kg; FATSCO—1800 mg/kg; and Protexall—2379 mg/kg.

FN37 Although the Terro product fans within category III, pure sodium arsenate fans within toxic category I, the most toxic category. 53 Fed.Reg. 24789.

FN38 In any event, an action taken by EPA in 1974 does not prevent the Agency in 1989 from acting to protect the public from a serious health threat. EPA's Special Review of the sodium arsenate ant baits did not commence until 1978. Moreover, it is unlikely that the Agency had the information available to it in 1974 that it now has on the large number of sodium ant bait poisonings that occur annually.

Senoret also maintains that Terro does not create an unreasonable risk because its LD50 for hamsters falls within a "moderately toxic" category according to Poisindex and Clinical Toxicology for Commercial Products, and its LD50 for hamsters is not sufficient to require Terro to be in child-resistant packaging under EPA regulations. See EPA Ex. 36 (pp. II-3 to II-4); Senoret Ex. 20, § 6.8A; 40 CFR § 157.22. Again, it is not merely the toxicity of Terro that creates the risk to human health, but rather a combination of its toxicity and the manner in which it is used. Because the product is placed on open bait stations around the home wherever ants are seen, there appears to be no way to keep the bait stations out of the reach of children. The regulation cited above does not preclude requiring child-resistant packaging for moderately toxic products where (as here) the risk of exposure is unreasonable (when viewed in conjunction with toxicity and then weighed against the benefits). See 40 CFR § 157.22(a)(6).

FN39 See EPA Ex. 39 (p. 1); Senoret Ex. 75 (p. 8).

FN40 The ALJ found that although a Terro cardboard bait station can reasonably hold approximately 1 ml of the bait, Terro is commonly placed on other types of bait stations such as wax

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paper, bottle caps, and pieces of bread. I agree. Terro poisoning has resulted from bait stations other than the cardboard squares. For example, the Blodgett Regional Poison Center reported that of the 187 reported cases of child exposure to Terro bait stations, 24.9% involved bait stations other than the cardboard squares. See EPA Ex. 8. Moreover, the record contains several letters from Senoret to customers recommending the use of wax paper and bottles caps, which can hold much more than 1 ml, as bait stations. See EPA Exs. 43-48. A bottle of Terro comes with six squares, which are not sufficient to dispense of the entire 29.6 ml (one ounce) bottle. Thus, it is to be expected that consumers will, after they have used up the six squares, utilize some other type of a bait station. See EPA Ex. 75; Tr. 1723-24. Moreover, the Terro label does not prescribe any specific amount to be placed on the cardboard, nor does it prohibit the use of other materials as bait stations. In fact, the label recommends mixing Terro with cooking oil to attract grease-eating ants, thereby making the use of the cardboard square impractical. See EPA Ex. 99. The Jones bait station holds 3.1 to 3.5 ml. EPA Ex. 40. There is evidence that a Terro square can hold 2-3 ml of the bait. See Tr. 1738-39. Thus, I accept the ALJ's conclusion that 2.5 ml of Terro is a reasonable amount to be expected to be found on a commonly used bait station. See also EPA Tr. Bf. (p. 37).

FN41 Likewise, the ALJ found a 7.4 kg child who ingested 2.5 ml of any of the other baits involved in this case would receive a dose of sodium arsenate that does not meet the one-tenth margin of safety. The child would receive the following doses from these products: Jones—8.1 mg/kg; Protexall—90 mg/kg; FATSCO—12.0 mg/kg

FN42 EPA's witness, Dr. Litovitz, estimated that the number of exposures reported to AAPCC was approximately 25% of the total number of exposures actually occurring in the United States. See EPA Ex. 7 (p. 9).

FN43 The ALJ found that 1 ml of Terro can reasonably be placed on the cardboard square bait stations that are sold with Terro.

FN44 Senoret also complains that the ALJ made certain findings regarding the effect of ingestion of an entire bottle of the ant bait products. As Senoret itself notes, however, the ALJ ultimately determined that the risk of drinking an entire bottle is not a widespread risk arising from the manner in which the product is used. Initial Decision at 49. The ALJ gave no weight to any such risk in his risk/benefit analysis, nor do I in today's decision.

FN45 See EPA Exs. 5, 136 (p. 199), 192 & 196; Senoret Exs. 12 (p. 2) & 21 (p. 86); Tr. 74-75, 716, 896, 932-933 & 946.

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FN46 See EPA Exs. 133 and 134.

FN47 The Dictionary of Epidemiology defines "exposure" as proximity or contact. See EPA Ex. 25 (emphasis added).

FN48 The record does contain a case, however, in which two or three acute ingestions may have caused peripheral neuropathy. See Tr. 540-543.

FN49 Of the 1475 exposures to sodium arsenate ant baits reported to the AAPCC in 1978, 403 were seen in a health care facility, 76 were admitted to a hospital, 45 were treated with BAL, 39 were treated with penicillamine, 370 were treated with syrup of ipecac, 187 were treated with activated charcoal, 133 were treated with a cathartic, and 23 were treated with lavage. See EPA Ex. 133.

FN50 Many experts agree that BAL therapy is of little or no benefit once the peripheral nerve and spinal cord are seriously involved. See EPA Ex. 147 (p. 8); 154 (p. 273).

FN51 Approximately 50% of all patients treated with BAL experience side effects, including high blood pressure, rapid pulse, nausea, vomiting, headaches and abscesses at the injection site. EPA Ex. 117 (p. 38). Senoret recognizes that "serious side effects and complications" can result from chelation. Senoret Proposed Findings (p. 13).

FN52 The average cost of treatment for sodium arsenate poisoning, including the cost of the emergency room, the hospital, and BAL therapy, is approximately $3,000 per patient. See EPA Ex. 118 (p. 20).

FN53 Pets that are exposed to sodium arsenate baits generally show more symptoms than do children. This may be a result of pets not receiving treatment as promptly as do children. Tr. 485.

FN54 Senoret also argues that the ALJ was unjustified in finding that persons with urine arsenic levels greater than 200 (micro)g/L were at risk because of treatment or potential side effects. Senoret's Exceptions (p. 69). I disagree. This finding was based on the Blodgett Regional Poison Center treatment protocol, which recommends treatment if a spot urine test shows a value greater than 200 (micro)g/L. See Initial Decision (pp. 38-40).

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FN55 The Grant's Ant Control Product, which contains arsenic trioxide in a sealed metal container, was exempted from the Notice of Intent to Cancel because it was not found to pose a hazard to the public. 53 Fed.Reg. 24,793.No determination is being made regarding the applicability of 40 CFR Part 164, Subpart D to a future application for registration of a sodium arsenate ant bait with a child-resistant bait station.

FN56 Throughout these proceedings, Senoret has maintained that sodium arsenate ant baits are effective for small infestations of "sweet-eating" ants. See, e.g. Senoret Proposed Findings (pp. 17-18). Nowhere in its post-trial brief, reply brief, or exceptions to the initial decision does Senoret argue that cancellation of such baits would result in an increased threat to human health or serious economic harm due to fire ants, pharaoh ants, or carpenter ants. The ALJ found that there is no evidence in the record that sweet-liquid sodium arsenate baits are effective against fire or pharaoh ants. See Initial Decision (p. 70). Although the ALJ suggested that there is some evidence that sodium arsenate baits are effective against carpenter ants, he did not find that the sodium arsenate baits are more effective than the alternative baits. Id. at 70-71.In fact, the record shows that poison baits in general, and sodium arsenate baits in particular, are not effective against carpenter ants in actual-use situations. See EPA Exs. 119 (pp. 16-22); 225 (p. 7). Every state that publishes recommendations for carpenter ant control recommends residual sprays or dusts as the best method for controlling carpenter ants. EPA Ex. 297. Thus, I find that Senoret has not demonstrated that sodium arsenate baits are effective against anything other than small infestations of sweet-eating ants.

FN57 Some of the alternative baits identified by Respondent include:

A. Hydramethylnon: Combat Ant Control System (see EPA Ex. 217) 0.9 **ydramethylnon, Reg. No. 1730-68; Combat Ant Control System Formula II (see EPA Ex. 288) 0.9% hydramethylnon, Reg. No. 1730-73**

B. Borax: Terro California Ant Killer (See EPA Ex. 296) 5.4% borax, Reg. No. 149-8; Black Leaf Ant Trap (see EPA Ex. 217) 5.4% borax, Reg. No. 5887-134; Magi-Kil Jelly (see EPA Ex. 296) 5.4% borax, Reg. No. 395-33; Pic Ant Trap (see EPA Ex. 217) 5.0% borax, Reg. No. 3095-24

C. Boric Acid: Drax (see EPA Exs. 217, 296) 5.0% boric acid, Reg. No. 44313-6; Antroll Ant Killer Formula II (see EPA Ex. 217) 2.0% boric acid, Reg. No. 475-237; Gator Ant Bait (see EPA Ex. 295) 4.5% boric acid, Reg. No. 60-3; Bug Wizard Ant Bait (see EPA Ex. 295) 6.0% boric acid, Reg. No. 49315-4; Protexall Ant-Kil (see EPA Ex. 295) 9.5% boric acid, Reg. No. 4972-23

D. Bendiocarb (FICAM): Tat-1 Ant Trap (see EPA Ex. 217) 0.03% bendiocarb, Reg. No.

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E. Propoxur (baygon): Black Flag Ant Trap Formula II (see EPA Ex. 217) 0.25ropoxur, Reg. No. 475-213; Tat Ant Trap (see EPA Ex. 217) 0.25% propoxur, Reg. No. 506-137; Nott Ant Trap (see EPA Ex. 296) 1.0% propoxur, Reg. No. 358-163; Grant's Ant Control (see EPA Ex. 296) 0.259% propoxur, Reg. No. 1663-29; Echols Roach, Ant and Waterbug Killer (see EPA Ex. 296) 2.0% propoxur, Reg. No. 3941-24; Antrol Ant Trap (see EPA Ex. 296) 2.0% propoxur, Reg. No. 475-173
F. Chlorpyrifos: Black Flag Ant Control System (see EPA Ex. 217) 0.5% chlorpyrifos, Reg. No. 475-254
G. Arsenic Trioxide: Grants Ant Control (see EPA Ex. 295) 0.46% arsenic trioxide, Reg. No. 1663-15.

FN58 FIFRA § 10(b) provides that "the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential ***."7 U.S.C. § 136h(b). Although FIFRA authorizes disclosure of CBI in a cancellation hearing if "necessary in the public interest," the Administrator must either obtain the registrant's consent or provide 30-days notice to afford the registrant an opportunity to contest the disclosure in federal district court. 7 U.S.C. § 136h(d)(2) and (3).

FN59 As discussed in more detail in Sections IV.C-E, three of Respondent's benefit witnesses presented testimony that was based in part on undisclosed CBI. Mr. Brassard testified on the efficacy of alternative ant bait products. While the vast majority of his testimony was not based on CBI, he did state that he had seen the confidential formula statements for the alternative ant baits and concluded that the inert ingredients would not lessen their efficacy against sweet-eating ants. Mr. Blondell, who testified primarily on the risks associated with the use of the sodium arsenate ant baits, also stated that he had reviewed CBI on the alternatives and concluded that their inert ingredients would not make them more toxic to humans than are the sodium arsenate baits. Mr. Dumas used confidential market share information obtained by EPA under FIFRA § 7 to calculate the total market share of the sodium arsenate ant baits.

FN60 See Greene v. McElroy, 360 U.S. 474 (1959) (Department of Defense reliance on confidential reports without allowing petitioner cross-examination opportunity was improper); Ohio Bell Tel. Co. v. Pub. Utils. Comm'n., 301 U.S. 292 (1937) (failure of Public Utilities Commission of Ohio to disclose price trend data, which the Commission relied upon, was improper); Wirtz v. Baldor Elec. Co., 337 F.2d 518 (D.C.Cir.1964) (Secretary of Labor's reliance on wage tables compiled from confidential information was improper where no opportunity for cross-examination

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was provided); Powhatan Mining Co. v. Ickes, 118 F.2d 105 (6th Cir.1941) (Department of Interior reliance on confidential price lists without permitting cross-examination was improper).

FN61 In its exceptions, Senoret argues that the ALJ should have stricken any testimony and exhibits based on undisclosed CBI. Senoret's Exceptions at 4; see also Id. at 11.By disregarding such evidence, I am effectively granting that relief. Respondent's actions regarding the CBI at issue are, to say the least, difficult to explain. It provided CBI to each of its witnesses on the benefits issue, solicited testimony at trial based in part on that CBI, refused to disclose the CBI to Petitioners, and then—instead of attempting to justify its conduct—now requests that any testimony based on the CBI be ignored. Although it does not say so expressly, Respondent virtually concedes that it has committed a tactical error, and now seeks to rescue its case by asking that the fruits of the CBI tree be segregated and disregarded. Although its candor on Appeal is appreciated, this difficulty was of its own making and could have been avoided by either shielding its experts from the CBI, obtaining the registrants' consent to disclosure, or providing the requisite notice under FIFRA.

FN62 See In re Velsicol Chemical Co., 41 Fed.Reg. 7552, 7554 (Feb. 19, 1976); In re Stevens Industries, Inc., 37 Fed.Reg. 13369, 13372-73. (June 14, 1972). Although Senoret recognizes that it has the burden of proving that the registered alternatives are ineffective (Senoret's Exceptions at 19), its Exceptions contain several assertions regarding Respondent's alleged failure to demonstrate their efficacy or availability. See, e.g., Id. at 26-27, 31, 34-35.The absence of record evidence on the relative efficacy of a registered alternative cuts against Senoret.

FN63 Typically, an initial lab screening is conducted on a large number of potential toxicants to determine wheter any exhibit a delayed toxicant effect on fire ants, on of the most difficult species to control.*See* Tr. 3407-22; Senoret Cross-examination Ex. 37.

FN64 In this study, worker ants were confined in a jar with 1.5% sodium arsenate bait, and the number of dead ants were then counted. *See* EPA Ex. 234. The study was not conducted in actual-use conditions, did not involve the whole colony or any brood or queens, and the ants had no competing food source available to them. No firm conclusions should be drawn about the efficacy of Jones ant killer from this study.*See* EPA Exs. 119 (p. 17); 225 (p. 17); & Tr. 3447-3448.

FN65 Senoret argues (Senoret's Exceptions at 39-40) that the Agency previously conceded the superiority of sodium arsenate ant baits in the Notice of Intent to Cancel, which states that such baits "are considered the most effective ant bait products for the control of sweet-eating ants."53 Fed.Reg. at 24,791.I disagree. The assertion that these baits "are considered" to be the most ef-

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fective is not inconsistent with finding, as the ALJ did, that in fact these products are only as effective as the alternatives. More importantly, statements in the Notice of Intent are not binding concessions or stipulations, but simply reflect the views of those who prepared the Notice when it was issued. Although such statements must be taken into account in a subsequent cancellation proceeding, they must be weighed against other record evidence. The very purpose of the trial is to critically examine the conclusions that led to the Notice. Here, the trial revealed that this particular assertion—one not essential to the decision to cancel when the notice was issued—was based on rather limited information. See, e.g., EPA Ex. 286; Senoret Exs. 93, 119; TR 3399-3400, 3623-24. Senoret's own expert, Dr. Traniello, recognized that the efficacy studies for sodium arsenate ant baits are subject to the same criticisms as those for the alternatives, and that firm efficacy conclusions require studies reflecting actual-use conditions, which are lacking for sodium arsenate ant baits. Finally, even if sodium arsenate baits were more effective, the alternatives (both bait and non-bait) are sufficiently effective to provide consumers with adequate options for the control of sweet-eating ants.

FN66 For example, efficacy studies showing positive results in sweet-eating ants have been conducted on the complete product, including the inerts, for the TAT-1 Ant Trap (bendiocarb) and Magi-kill Ant Bait (borax) on the little black ant, the thief ant, and the pavement ant. EPA Exs. 224, 284. See also EPA in camera exhibits 119, 238, 248 and 277. Although these in camera exhibits contain CBI, the respective registrants consented to Respondent's disclosure of this CBI to Senoret, and the CBI was in fact made available to Senoret in camera.

FN67 In fact, the President of Senoret, Mr. Roberts, testified that borax is effective against ants. See EPA Ex. 271 (p. 3).

FN68 Even if there were merit to Senoret's argument that it needed CBI on the inert ingredients of the alternatives to make its affirmative case, it was too late in the day for Senoret to wait until cross-examination at trial to attempt to compel disclosure of this information. EPA regulations provide procedures for resolving such issues prior to the trial. See 40 CFR § 264.50(a)(3), (9) & (11); 40 CFR § 164.51(a).

FN69 Mr. Brassard testified that there are 3845 total products registered for the control of household ants, approximately 50 of which are baits, leaving almost 3800 registered non-bait products available for ant control. EPA Ex. 119 (p. 5 and Table 3).

FN70 See EPA Exs. 274; 275; 276. EPA also demonstrated that there are nonchemical means of

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controlling ants, including sanitation and the blocking of entry points by filling cracks with caulking compound. EPA Exs. 119 (p. 10-11); 301.

FN71 Mr. Dumas is an economist in the Economic Analysis Branch of the Biological and Economic Analysis Division of EPA's Office of Pesticide Programs. He has two degrees in economics, including a Master of Science in Natural Resource Economics from the University of Massachusetts, and is currently a Ph.D. candidate in economics. Prior to joining EPA in 1986, he was a full-time faculty member in the Business and Economics Department at North Adams State College, where he taught a variety of economics and business courses. He has also taught economics on an adjunct basis at a number of other universities. See EPA Ex. 214 (p. 1).

FN72 Mr. Dumas provided a breakdown of the market shares of the commonly used ant bait products. He determined that the aggregate market share for all sodium arsenate ant bait products is between 4.0% and 4.8%. Because he relied on confidential information protected from disclosure under FIFRA § 7 in determining the market shares, Mr. Dumas could only disclose his final market share figures, which were not identified by product name or manufacturer.

FN73 The lack of information in the public literature on sodium arsenate ant baits, and on ant baits in general, corroborates Mr. Brassard's and Mr. Wagner's testimony that the use of residual pesticides, such as aerosol sprays, is often the preferred method of treating household ant problems. See EPA Exs. 219 (pp. 476-77), 230 (p. 134), 231 (p. 32); Tr 2738-40.

FN74 The four petitioners together sell about 1.2 million bottles of sodium arsenate annually. EPA Ex. 214 (p. 7).

FN75 This scenario grossly overestimates the cost of cancellation not only because it erroneously assumes the absence of effective alternatives, but also because the University of Nebraska survey on switching to professional control covered all household pesticide use. Thus, the 3-4% who switch to professional treatment includes consumers who hire professionals to control cockroaches, termites and other household pests. At least one study shows that consumers are much more likely to hire professionals to exterminate roaches than to control ants. EPA Ex. 311 (p. 33). Moreover, of the consumers with ant problems, common sense dictates that those with serious infestations probably account for a disproportionate share of those 3-4% who turn to professional treatment. There is no evidence that consumers will spend $25 to $75 to control the type of minor nuisance ant problems for which the sodium arsenate ant baits are used. I agree with Mr. Dumas that an individual predisposed to use ant bait products for minor infestations will continue to do so

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even when the product he normally uses is no longer available, rather than switching to an expensive pest control operator. See EPA Ex. 214 (p. 11).

Thus, the consequences of cancellation of the sodium arsenate ant baits will be, at worst, that consumers will tolerate small infestations of nuisance ants. Due to the large number of comparably priced alternatives, however, it is unlikely that this worst case scenario will occur.

FN76 Respondent filed an exception to the ALJ's denial of its motion to admit certain exhibits into evidence. The exhibits at issue—EPA exhibits 235, 237, 244, 247, 259 and 291—are records of communications between Mr. Brassard and independent entomology experts. It is well established that such hearsay evidence is admissible in administrative hearings. See Richardson v. Perales, 402 U.S. 389 (1971) (hearsay is admissible provided its use is fundamentally fair). Courts appear to be split, however, over whether such evidence is generally admissible or only if it meets certain criteria regarding reliability. Compare Johnson v. United States, 628 F.2d 187 (D.C.Cir.1980) (hearsay is generally admissible and may constitute substantial evidence) with Calhoun v. Bailor, 626 F.2d 145 (7th Cir.1980) (hearsay must meet a minimal threshold of reliability to be admissible), cert. denied452 U.S. 906 (1981).

In my view, general admissibility of hearsay is more consistent with Agency regulations governing cancellation proceedings. These rules require admission of all relevant, competent, and material evidence, unless unduly repetitious, regardless of whether the evidence would be admissible in federal court. See 40 CFR § 164.81(a). Any issues of reliability go only to weight. Id. Thus, hearsay exhibits should generally be admitted, with the weight to be determined by such indicia of reliability as the declarant's independence or possible bias, whether the exhibit was prepared in the ordinary course of business, whether the exhibit is of the kind routinely submitted in administrative proceedings, whether the opposing party had an opportunity to examine the exhibit prior to trial or to subpoena the declarant for testimony, whether the exhibit is corroborated or contradicted by other record evidence, and whether the exhibit is signed or sworn by the declarant (as opposed to anonymous). Accordingly, the exhibits at issue are admitted. Because they constitute cumulative evidence, however, it is not necessary for me to determine the precise weight to be given them in this proceeding.

2 E.A.D. 854, 1989 WL 550929 (E.P.A.)

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In the Matter of Reckitt Benckiser LLC, et al., FIFRA Docket No. 661

CERTIFICATE OF SERVICE

I certify that the foregoing **MOTION FOR AN EXPEDITED DETERMINATION THAT EPA'S EXISTING STOCKS DECISION IS WITHIN THE SCOPE OF THE HEARING**, dated April 12, 2013, was served at the addresses listed below in the manner indicated.

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Dated: **April 12, 2013**

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