UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF:

POUCH MAIL

June 25, 2008

Honorable Barbara A. Gunning
Administrative Law Judge
Office of the Administrative Law Judges
U.S. Environmental Protection Agency
Mail Code 1900L
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-2001

Re: *In the Matter of Behnke Lubricants, Inc.*
Docket No. FIFRA-05-2007-0025
Complainant's Post-Hearing Brief

Dear Judge Gunning:

Enclosed, please find a true, accurate and complete copy of Complainant's Post-Hearing Brief in the above-referenced matter. The original and one true, accurate and complete copy of Complainant's Post-Hearing Brief were filed with the Regional Hearing Clerk, Region 5, U.S. EPA, on June 25, 2008. A true, accurate and complete copy of Complainant's Post-Hearing Brief was delivered to Respondent's counsel, Mr. Bruce McIlnay, via Federal Express on June 25, 2008.

Should the Court have any questions, please do not hesitate to have your staff contact the undersigned at (312) 886-0813.

Sincerely,

James J. Cha
Associate Regional Counsel

cc: Mr. Bruce McIlnay, Esq.
McIlnay, Schmitt & Button, Ltd.
1150 Washington
Grafton, Wisconsin 53024
(Via Federal Express)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	
	)	
BEHNKE LUBRICANTS, INC.	)	**Proceeding to Assess a Civil Penalty**
MENOMONEE FALLS, WISCONSIN	)	**Under Section 14(a) of FIFRA,**
	)	**7 U.S.C. §136*l*(a)**
Respondent	)	
	)	**Docket No. FIFRA-05-2007-0025**
	)	
	)	

COMPLAINANT'S POST- HEARING BRIEF

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I. Introduction

In accordance with this Honorable Court's Order Setting Briefing Schedule, the United States Environmental Protection Agency, Region 5 (Complainant or U.S. EPA), through its undersigned attorneys, files the instant Complainant's Post-Hearing Brief, Proposed Findings of Fact (Section IX of this brief) and Proposed Conclusions of Law (Section X this brief), pursuant to the authority of Section 22.26 of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation, Termination or Suspension of Permits* (*"Consolidated Rules"*) 40 C.F.R. § 22.26.

II. Procedural Background

On May 7, 2007, Complainant ("U.S. EPA" or "the Agency") filed an eleven-count civil administrative Complaint against Behnke Lubricants, Inc. (Respondent or Behnke) pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. § 136*l*(a) for the assessment of a civil penalty. The Complaint alleges that on at least eleven different occasions, Respondent distributed or sold various unregistered pesticides in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A). U.S. EPA proposed a civil administrative penalty of $50,050. On June 8, 2007, Respondent filed its Answer and Request for a Hearing (Answer). On January 16, 2008, Complainant filed Complainant's Motion to Strike Affirmative Defenses and Complainant's Motion to Compel Discovery (Motion to Strike and Compel). On February 5, 2008, Respondent filed Respondent's Response to Complainant's Motion to Strike and Motion to Compel (Response to Motion to Strike and Compel). On January 22, 2008, U.S. EPA filed Complainant's Motion for

Accelerated Decision on Liability and on Affirmative Defenses (MAD). On February 21, 2008, Respondent filed Respondent's Response to Complainant's MAD. On February 27, 2008, Complainant filed its Reply to Respondent's Response to Complainant's MAD. On March 5, 2008, the Honorable Judge Gunning entered an Order Denying Complainant's Motion to Strike Respondent's Affirmative Defenses; Order Granting, In Part, and Denying, In Part, Complainant's Motion to Compel Discovery; Order Denying Complainant's Motion for Accelerated Decision on Liability and on Affirmative Defenses.

On March 31, 2008, Honorable Judge Gunning presided over a four day hearing in this matter in Waukesha County, Wisconsin. At the conclusion of the hearing, U.S. EPA demonstrated through a preponderance of the evidence that Respondent had violated FIFRA when it distributed or sold unregistered pesticides to its customers on at least eleven different occasions.

The Complainant also demonstrated through a preponderance of the evidence that it had calculated the proposed penalty of $50,050 in accordance with both the statutory factors listed in FIFRA and the applicable penalty policies. Furthermore, the Complainant demonstrated at hearing that Complainant's proposed penalty was conservative, and that Complainant could reasonably have calculated a much higher proposed penalty based on, among other things, the culpability factor in the FIFRA penalty policy. Thus, Complainant demonstrated the appropriateness of the penalty proposed in the Complaint.

III. Statutory and Regulatory Background

Section 3(a) of FIFRA, 7 U.S.C. § 136a(a), and 40 C.F.R. § 152.15 state in pertinent part that no person in any state may distribute or sell to any person any pesticide that is not registered under FIFRA. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), states that it is unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under Section 3 of FIFRA.

The regulation at 40 C.F.R. § 152.15(a)(1) states that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if the person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) that the substance can or should be used as a pesticide. The regulation at 40 C.F.R. § 168.22(a) states as follows:

> FIFRA Sections 12(a)(1)(A) and (B) make it unlawful for any person to "offer for sale" any pesticide if it is unregistered, or if claims made for it as part of its distribution or sale differ substantially from any claim made for it as part of the statement required in connection with its registration under FIFRA § 3. EPA interprets these provisions as extending to advertisements on any advertising medium to which pesticide users or the general public have access.

Section 2(s) of FIFRA, 7 U.S.C. § 136(s) defines a "person" as any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), and 40 C.F.R. § 152.3, in pertinent part, define "distribute and sell" as to "distribute, sell, offer for sale, hold for distribution, hold for shipment, or receive and (having so received) deliver or offer to deliver." Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.3, in pertinent part, define "pesticide" as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. Section 2(t) of FIFRA, 7 U.S.C.

§ 136(t), and 40 C.F.R. § 152.5(d), in pertinent part, define "pest" as "(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism."

IV. Factual Background

On August 3, 2006, an inspector employed by the Wisconsin Department of Agriculture, Trade and Consumer Protection (WDA) conducted an inspection under FIFRA at Respondent's place of business located at W134 N5373 Campbell Drive, Menomonee Falls, Wisconsin, 53051 (facility). (Complainants Exhibit (CX) 1, March 31, 2008 Transcript (Tr.)[1], 0051-0052 and ¶ 2 of Joint Stipulated Facts filed on March 12, 2008 (Joint Stips)). During that inspection, the inspector, (Mr. Jeff Saatkamp), collected physical samples of **JAX Poly-Guard FG-2** and **JAX Halo-Guard FG-2**. (CX 38 and CX 39; March 31 Tr., 0058-0059 and ¶ 3 of Joint Stips). These samples were found in the "warehouse manufacturing floor of the facility" "where they [(Behnke)] had their product stored and ready and released for shipment." (March 31 Tr., 0056 and ¶¶ 3, 11 and 15 of Joint Stips)[2].

The label on the physical sample of **JAX Poly-Guard FG-2** states in pertinent part, "Advanced, Anti-Wear NSF H1, Food Machinery Grease with PTFE and Micronox® Antimicrobial;" "The bonus is a H1 lubricating grease with Micronox® , JAX exclusive antimicrobial chemistry possessing true knockdown capabilities;" "powerful antimicrobial performance" and "added step in microbial protection programs." (CX 38; March 31 Tr., 0145 and ¶ 7 of Joint Stips). The label on the physical

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[1] The hearing was held on March 31, 2008 through April 3, 2008. Each separate day of transcript will be referred to hereinafter without the reference to the year 2008.

[2] Physical samples collected at the Behnke facility and received as CX 38 and CX 39 are

sample of the **JAX Halo-Guard FG-2** states in pertinent part, "JAX HALO-GUARD FG-2 provides Micronox® microbial knockdown performance." (CX 39; March 31 Tr., 0145 and ¶ 13 of Joint Stips).

During the inspection, the inspector also collected advertising literature for the following Behnke lubricants: **JAX Poly-Guard FG-2**, **JAX Halo-Guard FG-2**, **JAX Halo-Guard FG-LT** and **JAX Magna-Plate 74**. (CX1, at EPA 0005-0026; March 31 Tr., 0059-0060 and ¶ 4 of Joint Stips).

The literature for **JAX Poly-Guard FG-2** included the following statements:

(A) "Since June 1, 2001, JAX Poly-Guard FG contains Micronox®, providing antimicrobial protection for the product. JAX Micronox® has proven especially effective in protecting JAX Poly-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."
(B) "Powerful Antimicrobial Performance"
(C) "Added Step in Microbial Protection Programs"

(CX 1, at EPA 0021). The literature also included Respondent's contact information such as phone number, facsimile number and Internet address. (CX 1, at EPA 0022; and ¶ 6 of Joint Stips).

The literature for **JAX Halo-Guard FG-2** included the following statements:

"JAX Halo-Guard FG Greases incorporate JAX new, proprietary antimicrobial additive technology, Micronox®, to provide antimicrobial protection for the product. A first in food-grade lubricants, JAX Micronox has proven especially effective in protecting JAX Halo-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

(CX 1, at EPA 0023). The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address. (CX 1, at EPA 0024 and ¶ 12 of Joint Stips).

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the basis of counts 1 and 2 of the underlying Complaint.

The literature for **JAX Halo-Guard FG-LT** included the following statements:

"JAX Halo-Guard FG Greases incorporate JAX new, proprietary antimicrobial additive technology, Micronox®, to provide antimicrobial protection for the product. A first in food-grade lubricants, JAX Micronox has proven especially effective in protecting JAX Halo-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

(CX 1, at EPA 0023). The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address. (CX 1, at EPA 0024 and ¶ 16 of Joint Stips).

The literature for **JAX Magna-Plate 74** included the following statements:

(A) "JAX Magna-Plate 74 incorporates JAX new, proprietary antimicrobial additive technology, Micronox®, for enhanced antimicrobial protection for the product against a wide variety of microbial agents, including yeasts, molds, and gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox® has proven especially effective in protecting the product against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium)."
(B) "JAX Magna-Plate 74 provides three major benefits to food and beverage processing plants ... Micronox® anti-microbial technology to provide antimicrobial protection for the product..."
(C) "Powerful Antimicrobial Performance"
(D) "Added Step in Microbial Protection Programs"

(CX 1, at EPA 0025). The literature included information about container sizes and part numbers in addition to Respondent's contact information, which included a phone number, facsimile number and Internet address. (CX 1, at EPA 0026 and ¶ 19 of Joint Stips).

Prior to the August 3, 2006, inspection, Mr. Saatkamp also performed an internet search on June 23, 2006, at www.meatpoultry.com which featured a promotional story on Magna Plate-74 which stated, among other things:

(A) "In an effort to combat Listeria and other harmful microbial agents in air-operated equipment, Behnke Lubricants Inc/JAX has introduced Magna Plate-74 with Micronox®..."

(B) "Magna-Plate 74 contains JAX's Micronox® technology, a revolutionary food-grade antimicrobial agent that provides unsurpassed protection against potentially deadly bacterial contamination such as E-coli, Listeria and Salmonella."
(C) "Magna-Plate 74 provides various benefits to food and beverage processing plants, including: longer bearing and air operated equipment life; Micronox® antimicrobial technology to knockdown and prevent growth in the air system..."

The article also stated: "JAX lubrication products are distributed worldwide. For information about JAX products, consumers can call toll-free 1-800-782-8850, or email requests to info@jax.com." (CX 1a and March 31 Tr., 0053-0055).

During the August 3, 2006 inspection of the Behnke facility, Mr. Saatkamp also collected shipping records which demonstrated that Respondent had distributed or sold **JAX Poly-Guard FG-2** to Perlick Corporation (Perlick) on March 3, 2006[3] (CX 1 at EPA 0028 and ¶ 9 of Joint Stips) and to Badger Plastics & Supply, Inc (Badger) on June 15, 2006[4] (CX 1 at EPA 0027 and ¶ 10 of Joint Stips); that Respondent had distributed or sold **JAX Poly-Guard FG-LT** to Faribault Foods on February 11, 2006 (CX 1 at EPA 0029 and ¶ 39 of the Answer) and to Pepsi Cola on June 6, 2006 (CX 1 at EPA 0030 and ¶ 40 of Answer)[5]; that Behnke had distributed or sold **JAX Halo-Guard FG-2** to B-Way Corporation on March 14, 2006 (CX 1 at EPA 0034 and ¶ 51 of Answer), to Badger on June 15, 2006 (CX 1 at EPA 0027 and ¶ 52 of Answer) and to Seneca Foods (Seneca) on July 14, 2006 (CX 1 at EPA 0033 and ¶ 53 of Answer); that Respondent had distributed or sold **JAX Halo-Guard FG-LT** to KHS, Inc. (KHS) on April 7, 2006 (CX 1 at EPA

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[3] This shipping record is the basis of Count 11 in the Complaint.

[4] This shipping record is the basis of Count 9 in the Complaint.

[5] Although U.S. EPA did not allege these particular distributions or sales as violations in the Complaint, it is important to note the widespread violations relating to Behnke's lubricants containing Micronox antimicrobial technology.

0031 and ¶ 63 of Answer and to Jennie-O Turkey Store (Jennie-O) on June 27, 2006[6] (CX 1 at EPA 0032 and ¶ 18 of Joint Stips); that Behnke had distributed or sold **JAX Magna-Plate 74** to Sara Lee Foods (Sara Lee) on July 11, 2006 (CX 1 at EPA 0035 and ¶ 77 of Answer) and to American Foods Group (American) on March 3, 2006[7] (CX 1 at EPA 0036 and ¶ 21 of Joint Stips); and that Respondent had distributed or sold **JAX Magna-Plate 78** to American on March 3, 2006[8]. (CX 1 at EPA 0036 and¶ 33 of Joint Stips).

On March 7 and 8, 2008, U.S. EPA conducted numerous follow-up investigations at facilities owned by some of Behnke's customers, where the lubricants were in actual use. The purpose of these follow-up investigations was to verify that Behnke was making the labeling and advertising claims that were discovered at the Behnke facility on August 3, 2006, to Respondent's customers. (CX 8[9], 8a, 8b, 8c, 9, 10, 11, 12, 12a, 13, and 15).

On March 8, 2007, U.S. EPA conducted an investigation at American located at Acme Street, Green Bay, Wisconsin (CX 8 and ¶ 22 of Joint Stips). This facility is known as the Acme plant. (March 31 Tr. 0080-0081). During that investigation, Mr. Josh Rybicki of American, gave the U.S. EPA inspector, Mr. Terence Bonace, copies of two purchase orders showing that American had ordered **JAX Halo-Guard FG-2** and

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[6] This shipping record is the basis of Count 10 in the Complaint.

[7] This shipping record is the basis of Count 7 of the Complaint.

[8] This shipping record (which can also be found in CX 8,at EPA 0182) is the basis of Count 6 of the Complaint.

[9] Note that CX 8 was received into the record on March 31, 2008 despite the fact that the index of the March 31, 2008 transcript does not show that it was received into the record. (March 31 Tr., 0222).

JAX Magna-Plate 78 on December 19, 2006[10], and that American had ordered **JAX Magna-Plate 78** on March 5, 2007[11]. (CX 8, at EPA 0194 and EPA 0193, March 31 Tr., 0155-0156 and ¶¶ 30 - 32 of Joint Stips). After the investigation, Mr. Rybicki sent Mr. Bonace three separate pieces of literature that American had received from Behnke. (CX 8a, CX 8b and CX 8c.)

The first piece of advertising literature that the U.S. EPA inspector received from Mr. Rybicki was entitled "American Foods Group, JAX Lube-Guard Program" (dated June 20, 2003), and included, among other things, the following information:

(A) Literature for **Magna-Plate 78 Fluids** which stated, among other things: "Antimicrobial Performance: Both products incorporate JAX new, proprietary antimicrobial additive technology, Micronox™ for enhanced product protection against a wide variety of microbial agents, including yeasts, molds, gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox™ provides significant knockdown performance and has proven especially effective against lysteria (Lysteria monocytogenes), E. coli (Escherichia coli) and salmonella (Salmonella typhimurium) on contact and over extended lubrication intervals." (CX 8a, at EPA 0208).
(B) This literature also included the Respondent's contact information such as phone number, facsimile number and Internet address. (CX 8a, at EPA 0209).
(C) Literature for **Magna-Plate 74** which stated, among other things: "Antimicrobial Performance: JAX Magna-Plate 74 incorporates JAX new, proprietary antimicrobial additive technology, Micronox®, for enhanced antimicrobial protection against a wide variety of microbial agents, including yeasts, molds, and gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox® provides significant knockdown performance and has proven especially effective against lysteria (Lysteria monocytogenes), E. coli (Escherichia coli) and salmonella (Salmonella typhimurium) on contact and over extended lubrication intervals." (CX 8a, at EPA 0210).
(D) This literature also included the Respondent's contact information such as phone number, facsimile number and Internet address. (CX 8a, at EPA 0211).
(E) The packet also included literature for **Halo-Guard FG** which stated, "JAX Halo-Guard FG provides Micronox® microbial knockdown performance." (CX 8a, at EPA 0202). Behnke's contact information (phone no., fax no. and website address) was also provided. (CX 8a., at EPA 0203).

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[10] This shipping record was the basis of Counts 3 and 4 of the Complaint.

[11] This shipping record was the basis of Count 5 of the Complaint.

The second piece of advertising literature that Mr. Bonace received from Mr. Rybicki was entitled "JAX Lubricant Guide for Food, Beverage, Drug & Cosmetic Processing & Manufacturers" (CX 8b) and included, among other things, the following:

(A) A cover letter addressed to the customer, which stated: "First and foremost is Micronox®, JAX advanced antimicrobial technology that provides immediate and significant knockdown performance on a wide spectrum of microbial contaminants. This development alone is providing HACCP programs a powerful new weapon in their ongoing battle against microorganisms." (CX 8b, at EPA 0242).
(B) A sheet entitled "JAX Micronox® Technology" which describes in detail the enhanced antimicrobial capabilities of the Micronox® additive system, including a graph purporting to compare Poly-Guard FG with competitor products in terms of their efficacy against Listeria, E. coli, and Salmonella. (CX 8b, at EPA 0249).
(C) The literature also included the Respondent's contact information such as phone numbers and facsimile numbers (for both Behnke's Headquarters office and its Sacramento, CA, Western Regional Warehouse). (CX 8b, at EPA 0251).

The third and final piece of advertising literature that the U.S. EPA inspector received from Mr Rybicki was entitled "Technology Focus, JAX Micronox™ Technology, Introducing Micronox™ Technology in JAX Food-Grade Lubricants for Microbial Knockdown Performance against Listeria, E. coli, Salmonella and other microorganisms" (CX 8c), and which included, among other things:

(A) A letter from the Behnke Technical Director entitled: "What is JAX Micronox™ Technology: Re: Antimicrobial Usage in JAX Food-Grade Products." (CX 8c, at EPA 0256).
(B) Literature for **Poly-Guard Greases** which made many claims regarding its antimicrobial capabilities and performance due to Micronox™. (CX 8c, at EPA 0257).
(C) Literature for **Magna Plate 78** which made many claims regarding its antimicrobial capabilities and performance due to Micronox™. (CX 8c, at EPA 0259-60).
(D) Literature entitled "Plant Microbial Knockdown Results" which included references to **JAX Poly-Guard FG-2** and its antimicrobial features. (CX 8c, at EPA 0270).
(E) Literature entitled "Major Food Processor Lab Test Results" which also made references to **JAX Poly-Guard FG-2** and its antimicrobial features. (CX 8c, at EPA 0271).
(F) Literature entitled "Independent Lab Results" which also made references to **JAX Poly-Guard FG-2** and its antimicrobial features. (CX 8c, at EPA 0272).
(G) Literature entitled "Food Industry Firsts" that stated, among other things: "The first effective food-grade antimicrobial additive for lubricants with knockdown capabilities, effectively partnering lubricants into plant sanitation programs." (CX 8c, at EPA 0274).

(H) The literature also included contact information for Respondent including Respondent's phone number, facsimile number, Internet address, distributor information (including the names, telephone numbers and email addresses of Behnke's Regional Managers) and product ordering options. (CX 8c, at EPA 0276, March 31 Tr., 0156-0165 and ¶¶ 24-28 of Joint Stips).

Mr. Rybicki confirmed at the time of hearing that he had received all three pieces of advertising literature from Behnke. (March 31 Tr., 0092–0094).

Additionally, CX 16a (see page 2 of Joint Set of Stipulated Exhibits and Joint Motion to Admit Exhibits Into Evidence, filed on March 12, 2008) is further evidence that Behnke distributed or sold **JAX Poly-Guard FG-2**, **JAX Magna Plate-74** and **JAX Magna-Plate 78** to American on many occasions between May 29, 2002 and May 7, 2007. While this evidence shows the great breadth of Behnke's violations, given the late date in which U.S. EPA obtained this evidence, the Agency exercised its enforcement discretion and opted to present this evidence only to demonstrate the gravity of the violations, rather than to amend the Complaint to include many additional counts[12].

On March 8, 2007, Mr. Bonace visited Badger, located at 3451 Johnson Avenue in Plover, Wisconsin. (CX 9). Badger distributes Behnke's lubricants to end users. During that investigation, Mr. Bonace was taken to a supply area by one of Badger's employees. Mr. Bonace observed four boxes, each containing ten 14-ounce cartridge tubes of **JAX Poly-Guard FG-2** in the storage area. Mr. Bonace inspected a single tube from each of the four boxes and determined that each tube bore identical language on it,

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[12] It is also worth noting that Mr. Bonace testified that, even on the first day of the actual hearing, Behnke continued to make public health antimicrobial pesticidal claims on its websites and associated web links. (March 31 Tr., 0201-0202; and April 2 Tr., 0629-0632, 0706). Further, Respondent's own witness, company President Eric Peter, testified that Behnke continues to use the words "Micronox" and "antimicrobial" on the labels of more than 80 of its lubricants containing the Micronox antimicrobial technology. (April 2 Tr., 0652-0653).

which included claims such as "Advanced, Anti-Wear NSF H1, Food Machinery Grease with PTFE and Micronox® Antimicrobial[,]" "[t]he bonus is an H1 lubricating grease with Micronox®, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs." Mr. Bonace also noted that the tubes of **JAX Poly-Guard FG-2** found at Badger were identical to the physical sample of **JAX Poly-Guard FG-2** that was obtained by the WDA inspector on August 3, 2006 at the Behnke facility. Mr. Bonace also took a photograph of one of these tubes of JAX Poly-Guard FG-2, which photograph is included in his inspection report. (CX 9, at EPA 0283; March 31 Tr., 0165-0168 and ¶¶ 34-39 of Joint Stips).

During the investigation, Badger also provided Mr. Bonace with advertising literature concerning Behnke's lubricants. (CX 9, at EPA 0284-0286). The advertising literature was entitled "Food Grade Lubricants with Micronox™," and included a document entitled "What is JAX Micronox™ Technology? Re: Antimircrobial Usage in JAX Food-Grade Products." This latter document consisted of a memorandum signed by Mr. Troy F. Paquette, Behnke's Technical Director, which described the purported antimicrobial capabilities of the Micronox™ technology found in Respondent's food grade lubricants. (CX 9, at EPA 0285). The advertising literature also included tables and a graph illustrating the "antimicrobial properties" of **JAX Poly-Guard FG-2** "antimicrobial grease" and its purported efficacy against Listeria, E. coli and Salmonella. (CX 9, at EPA 0285). This literature also included contact information for Respondent, including Respondent's phone number, facsimile number, website, distributor

information and product ordering options. (CX 9, at EPA 0286; March 31 Tr., 0166-0167 and ¶¶ 40-44 of Joint Stips.)

During the investigation, Badger also gave Mr. Bonace copies of two invoices that showed that Respondent had distributed or sold **JAX Halo-Guard FG-2** and **JAX Poly Guard FG-2** to Badger on June 15, 2006, and September 18, 2006[13]. (CX 9, at EPA 0281-82; March 31 Tr., 0168, and ¶ 45 of Joint Stips).

On March 7, 2007, Mr. Bonace conducted an investigation at Perlick, located at 8300 West Good Hope Road, Milwaukee, Wisconsin. (CX 10). During that investigation, Mr. Bonace viewed and photographed a 14-ounce cartridge of **JAX Poly-Guard FG-2**. (CX 10, at EPA 0291). The cartridge of **JAX Poly-Guard FG-2** included the following language: "Advanced, Anti-Wear NSF H1, Food Machinery Grease with PTFE and Micronox® Antimicrobial," "The bonus is an H1 lubricating grease with Micronox®, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs." The cartridge of **JAX Poly-Guard FG-2** was identical to the physical sample of **JAX Poly-Guard FG-2** that was obtained on August 3, 2006 during the Behnke inspection. (March 31 Tr., 0168-170 and ¶¶ 50 - 53 of Joint Stips).

On March 7, 2007, the State of Minnesota Department of Agriculture conducted an inspection at Jennie-O, located at 1530 30th Street SW, Willmar, Minnesota, at the request of U.S. EPA. (CX 15). During the inspection, the inspector viewed and photographed a cartridge tube of **JAX Halo-Guard FG-LT** and confirmed that Jennie-O had ordered **JAX Halo-Guard FG-LT** from Behnke on or about June, 2006. (CX 15, at

[13] This shipping record is the basis for Count 8 of the Complaint.

EPA 0351-a through EPA 0354-b). The labeling on the tube of **JAX HALO-Guard FG-LT** stated "JAX Halo-Guard FG-LT provides Micronox® microbial knockdown performance" (CX 15, at EPA 0353-a and EPA 0353-b; March 31 Tr., 0219 and ¶¶ 46-49 of Joint Stips).

On March 8, 2007, Mr. Bonace conducted an investigation at Sara Lee[14], located at N3620 County Road D, New London, Wisconsin. (CX 11). During the investigation, Mr. Bonace viewed and photographed a 14-ounce cartridge of **JAX Poly-Guard FG-2**. (CX 11, at EPA 0297-0298). The cartridge of **JAX Poly-Guard FG-2** included the following language: "Advanced, Anti-Wear NSF H1, Food Machinery Grease with PTFE and Micronox® Antimicrobial," "The bonus is an H1 lubricating grease with Micronox®, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs." (CX 38 and March 31 Tr., at 0144, 0170-0171.) The cartridge of **JAX Poly-Guard FG-2** was identical to the physical sample of **JAX Poly-Guard FG-2** that was obtained on August 3, 2006 during the Behnke inspection. (CX 38). Sara Lee also gave Mr. Bonace a copy of a purchase order that showed that Sara Lee had purchased **JAX Poly-Guard FG-2** from Badger on or about February 12, 2007[15]. (CX

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[14] While U.S. EPA did not allege violations relating to any distribution or sale by Behnke to Sara Lee (despite the fact that there is evidence to show that Behnke sold **JAX Magna-Plate 74** to Sara Lee on or about July 11, 2006 (see CX 1)), it is important to note that the evidence reveals how Behnke engaged in widespread advertising that made explicit and implicit antimicrobial pesticidal claims regarding the JAX lubricants containing Micronox antimicrobial technology.

[15] While the U.S. EPA did not allege a violation based on this purchase order, it is important to note that this evidence of distribution or sale shows the breadth of Respondent's violations with regard to its lubricants containing Micronox antimicrobial technology. This underscores both the importance of asserting FIFRA regulatory jurisdiction over Respondent's products, and the need to deter Respondent's illegal

11, at EPA 0296 ("GREASE, INDUSTRIAL: FOOD GRADE, POLY-GUARD ...," March 31 Tr., 0144, 0170-0171 and 0217-0218; and page 12 of Behnke's Response to MAD).

On March 7, 2007, Mr. Bonace conducted an investigation at Seneca[16], located at 640 Caughlin Road, Clyman, Wisconsin. (CX 12). During the investigation on March 7, 2007, Seneca provided the inspector with information sheets that Seneca had received from Behnke. The first information sheet was entitled: "JAX MAGNA-PLATE 72, USDA H1-AUTHORIZED AIR LINE LUBE WITH ANTIRUST AND ANTIWEAR ADDITIVES NOW WITH MICRONOX® ANTIMICROBIAL TECHNOLOGY," and included the following language:

"Antimicrobial Performance: JAX MAGNA-PLATE 72 incorporates JAX new, proprietary antimicrobial additive technology, Micronox®, for enhanced antimicrobial protection against a wide variety of microbial agents, including yeast, molds, gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox® provides significant knockdown performance and has proven especially effective against (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) on contact over extended lubrication intervals."

(CX 12, at EPA 0307).

The second information sheet was entitled: "JAX MAGNA-PLATE 78 USDA H1-AUTHORIZED EXTREME - PRESSURE FOOD MACHINERY OIL WITH ENHANCED ANTIWEAR PROPERTIES NOW WITH MICRONOX® ANTIMICROBIAL TECHNOLOGY," and included the following language:

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conduct.

[16] While U.S. EPA did not allege violations relating to any distribution or sale by Behnke to Seneca (despite the fact that there is evidence to show that Behnke sold **JAX Halo-Guard FG-2** to Seneca on or about July 14, 2006 (See CX 1)), it is important to note that the evidence shows that Behnke was engaging in widespread advertising which made explicit and implicit pesticidal claims for the JAX lubricants containing Micronox antimicrobial technology.

"Antimicrobial Performance: JAX MAGNA-PLATE 78 incorporates JAX new, proprietary antimicrobial additive technology, Micronox™, for enhanced antimicrobial protection against a wide variety of microbial agents, including yeast, molds, gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox™ provides significant knockdown performance and has proven especially effective against (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) on contact and over extended lubrication intervals."

(CX 12, at EPA 0308).

The third information sheet was entitled: "HALO-GUARD FG GREASES" and included the following language: "JAX Halo-Guard FG provides Micronox® microbial knockdown performance." (CX 12, at EPA 0310).

The final information sheet was entitled "JAX POLY-GUARD FG, A REVOLUTIONARY USDA-H1 FOOD-GRADE GREASE W/PTFE FOR LUBRICATION OF HIGH-SPEED/HIGH-TEMP FOOD AND BEVERAGE PROCESSING MACHINERY NOW WITH MICRONOX® ANTIMICROBIAL TECHNOLOGY" and included the following language:

"Antimicrobial Performance: JAX POLY-GUARD FG incorporates JAX new, proprietary antimicrobial additive technology, Micronox®, for enhanced antimicrobial protection against a wide variety of microbial agents, including yeast, molds, gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox® provides significant knockdown performance and has proven especially effective against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) on contact and over extended lubrication intervals."

(CX 12 at EPA 0312).

On or about March 12, 2007, Seneca forwarded an electronic mail message to U.S. EPA. This email message had been sent to Seneca by Behnke on or about October 26, 2006. (CX 12a and March 31 Tr., 0172). The October 26, 2006 email message from Behnke to Seneca, which was entitled "Halo Guard and Poly Guard Data Sheets," had two data sheets attached to it for **JAX Halo-Guard FG Series** and **JAX Poly-Guard**

Series Greases. The first information sheet was entitled "HALO-GUARD FG GREASES" and included the following language:

"Antimicrobial Performance: JAX Halo-Guard FG Greases incorporate JAX new, proprietary antimicrobial additive technology, Micronox®, to provide antimicrobial protection for the product. A first in food-grade lubricants, JAX Micronox® has proven especially effective in protecting JAX Halo-Guard FG Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium), over extended lubrication intervals."

(CX 12, at EPA 0303). The second information sheet was entitled "POLY-GUARD FG-LT, FG-2" and included the following language:

"Since June 1, 2001 JAX Poly-Guard FG contains Micronox®, providing antimicrobial protection for the product. JAX Micronox® has proven especially effective in protecting JAX Poly-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

(CX 12, at EPA 0305, CX 12a, at EPA 0321a, CX 12, at EPA 0303-06, March 31 Tr., 0171-0173 and 0218-0219, page 12 of Response to MAD).

On March 19, 2007, Mr. Bonace received a copy of an advertising brochure from KHS, located in Waukesha, Wisconsin. (CX 13). The back cover of the brochure was marked "JAX Products Distributed by: Behnke Lubricants, Inc. - JAX" and included Respondent's phone and facsimile numbers in Menomonee Falls, Wisconsin and Sacramento, California. (CX 13, at EPA 0323). The brochure was entitled "JAX: Lubricant Guide For Food, Beverage, Drug & Cosmetic Processing & Manufacturing." (CX 13, at EPA 0323). The brochure included a letter from Respondent to its customers which included the following language:

"Micronox®, JAX advanced antimicrobial additive technology that provides immediate and significant knockdown performance on a wide spectrum of microbial contaminants. This development alone is providing HACCP programs a powerful weapon in their ongoing battle against microorganisms ..." "JAX Poly-Guard® FG is a new concept in food-grade greases, providing the highest level of antiwear performance of any competitor, and the benefits of Micronox®."

(CX 13, at EPA 0324). The brochure also included a table of contents which included a section entitled "Micronox® Antimicrobial Technology." The "Micronox® Antimicrobial Technology" section described in detail the enhanced antimicrobial capabilities of Micronox® technology. (CX 13, at EPA 0331; March 31 Tr., 0173-0174 and page 12 of Response to MAD).

Mr. Bonace also conducted numerous Internet searches to determine if Behnke was making advertising claims on the Internet that were pesticidal in nature. On June 9, 2006 (CX 3 and March 31 Tr., 0134-0140), November 17, 2006 (CX 4 and March 31 Tr., 146-0148), February 26, 2007 (CX 5 and March 31 Tr., 0151-0152), March 21, 2007 (CX 6a, March 31 Tr., 0175-0178), March 26, 2007 (CX 6b and March Tr., 0178-0179), April 10, 2007 (CX 6c and March Tr., 0179-0184), and March 31, 2008 (March 31 Tr., 0195-0197 and 0201-0202), Mr. Bonace found that Behnke continued to make pesticidal claims on the Internet with respect to its JAX lubricants containing Micronox antimicrobial technology, and in particular with respect to **JAX Poly-Guard FG-2**, **JAX Halo-Guard FG-2**, **JAX Halo-Guard FG-LT**, **JAX Magna-Plate 74** and **JAX Magna-Plate 78**. Additionally, Mr. Bonace found that Behnke continued to make pesticidal claims on the Internet even on the day of the hearing (March 31 Tr., 0201-0202; and April 2 Tr., 0629-0632, 0706).

Complainant's Proposed Findings of Fact (Section IX) and Proposed Conclusions of Law (Section X) are attached to this Post-Hearing Brief.

V. Standard of Proof

In an administrative penalty action initiated under the Consolidated Rules, the standard of proof is the "preponderance of the evidence." 40 C.F.R. § 22.24(b). Under 40 C.F.R. § 22.24(a), U.S. EPA bears "the burdens of presentation and persuasion that the violation[s] occurred as set forth in the Complaint and that the relief sought is appropriate." Under a preponderance of the evidence standard, the evidence is weighed to determine its weight and persuasiveness. Under this standard, the proponent must show that the evidence as a whole proves that the facts sought to be proven are more probable or likely than not to have occurred. As the Environmental Appeals Board ("EAB" or "the Board") has observed, the complainant has the burden of going forward with and providing evidence that the violation occurred. *In the Matter of Sandoz*, Inc., 2 E.A.D. 324 (EAB 1987). Under a preponderance of the evidence standard, the evidence is weighed to determine its weight and persuasiveness.

VI. Elements of Proof

Complainant alleges that Respondent has violated Section 3(a) and Section 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A) by distributing or selling pesticides that are not registered under FIFRA on at least eleven separate occasions. U.S. EPA must show through the documentary, physical and testimonial evidence in the record that it is entitled to a judgment in its favor with respect to liability and penalty.

In order to prove liability for each of the eleven counts, the U.S. EPA must prove (1) Behnke is a "person," as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s); (2) in "any state;" (3) Behnke distributed and sold a product, as defined by Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg); (4) the product Behnke sold was a pesticide, as defined by

Section 2(u) of FIFRA, 7 U.S.C. § 136(u); and (5) the product was not registered as a pesticide under Section 3 of FIFRA, 7 U.S.C. § 136a.

A. Behnke is a "person" "in any state"

In its Answer, Behnke admits that it is a corporation organized under the laws of the State of Wisconsin with a place of business located at W134 N5373 Campbell Drive, Menomonee Falls, Wisconsin. (¶ 3 of the Answer, ¶ 1 of Joint Stips, page 11 of Response to MAD). Behnke further admits that it is a "person" as that term is defined in Section 2(s) of FIFRA, 7 U.S.C. § 136(s). (¶ 13 of the Answer and page 11 of Response to MAD). Therefore, there is no dispute with respect to these two elements of proof. Behnke is a "person" doing business in the state of Wisconsin.

B. Behnke "distributed or sold" a product

In each of the eleven counts, Complainant alleges that Behnke distributed or sold a lubricant to one of its customers. Respondent admits that it distributed or sold its lubricants on the dates and to the customers alleged in each of the eleven counts.

1. Count I

In Count I, Complainant alleges that, on or about August 3, 2006, Behnke distributed or sold **JAX Poly-Guard FG-2**. It is undisputed that on or about August 3, 2006, Behnke distributed or sold **JAX Poly-Guard FG-2** (¶ 30 of Answer, ¶ 3 of Joint Stips, page 11 of Response to MAD).

2. Count II

In Count II, Complainant alleges that on or about August 3, 2006, Behnke distributed or sold **JAX Halo-Guard FG-2**. It is undisputed that on or about August 3,

2006, Respondent distributed or sold **JAX Halo-Guard FG-2.** (¶ 54 of the Answer, ¶ 3 of Joint Stips and page 11 of Response to MAD).

3. Count III

In Count III, Complainant alleges that on or about December 19, 2006, Behnke distributed or sold **JAX Halo-Guard FG-2** to its customer, American. It is undisputed that on or about December 19, 2006, Respondent distributed or sold **JAX Halo Guard FG-2** to American in Green Bay, Wisconsin. (¶ 101 of the Answer, ¶ 30 of Joint Stips, page 11 of Response to MAD).

4. Count IV

In Count IV, Complainant alleges that on or about December 19, 2006, Behnke distributed or sold **JAX Magna-Plate 78** to its customer, American. It is undisputed that on or about December 19, 2006, Respondent distributed or sold **JAX Magna-Plate 78** to American in Green Bay, Wisconsin. (¶ 102 of the Answer, ¶ 31 of Joint Stips and page 11 of Response to MAD).

5. Count V

In Count V, Complainant alleges that on or about March 5, 2007, Behnke distributed or sold **JAX Magna-Plate 78** to its customer, American. It is undisputed that on or about March 5, 2007, Respondent distributed or sold **JAX Magna-Plate 78** to American in Green Bay, Wisconsin. (¶ 103 of the Answer, ¶ 32 of Joint Stips and page 11 of Response to MAD).

6. Count VI

In Count VI, Complainant alleges that on or about March 3, 2006, Behnke distributed or sold **JAX Magna-Plate 78** to its customer, American. It is undisputed that

on or about March 3, 2006, Respondent distributed or sold **JAX Magna-Plate 78** to American in Green Bay, Wisconsin. (¶ 104 of the Answer, ¶ 33 of Joint Stips, page 12 of Response to MAD).

7. Count VII

In Count VII, Complainant alleges that on or about March 3, 2006, Behnke distributed or sold **JAX Magna-Plate 74** to its customer, American. It is undisputed that on or about March 3, 2006, Respondent distributed or sold **JAX Magna-Plate 74** to American in Green Bay, Wisconsin. (¶¶ 78 and 105 of the Answer, ¶ 21 of Joint Stips and page 12 of Response to MAD).

8. Count VIII

In Count VIII, Complainant alleges that on or about September 18, 2006, Behnke distributed or sold **JAX Poly-Guard FG-2** to its customer, Badger. It is undisputed that on or about September 18, 2006, Respondent distributed or sold **JAX Poly-Guard FG-2** to Badger in Plover, Wisconsin. (¶ 45 of Joint Stip, page 12 of Response to MAD).

9. Count IX

In Count IX, Complainant alleges that on or about June 15, 2006, Behnke distributed or sold **JAX Poly-Guard FG-2** to one of its customers, Badger. It is undisputed that on or about June 15, 2006, Respondent distributed or sold **JAX Poly-Guard FG-2** to Badger located in Plover, Wisconsin. (¶¶ 29 and 124 of the Answer, ¶ 10 of Joint Stips, page 12 of Response to MAD).

10. Count X

In Count X, Complainant alleges that on or about June 27, 2006, Behnke distributed or sold **JAX Halo-Guard FG-LT** to one of its customers, Jennie-O. It is

undisputed that on or about June 27, 2006, Respondent distributed or sold **JAX Halo-Guard FG-LT** to Jennie-O located in Wilmar, Minnesota. (¶¶ 64 and 130 of the Answer, ¶ 18 of the Joint Stips, page 12 of the Response to MAD).

11. Count XI

In Count XI, Complainant alleges that on or about March 3, 2006, Behnke distributed or sold **JAX Poly-Guard FG-2** to one of its customers, Perlick. It is undisputed that on or about March 3, 2006, Respondent distributed or sold **JAX Poly-Guard FG-2** to Perlick located in Milwaukee, Wisconsin. (¶¶ 28 and 136 of the Answer, ¶ 9 of the Joint Stips, page 12 of the Response to MAD).

C. The lubricants distributed or sold by Behnke were not registered as pesticides under FIFRA

In each of the eleven counts, Complainant alleges that the products that were distributed or sold by Behnke were not registered as pesticides under FIFRA. It is undisputed that none of the lubricants in question were registered under FIFRA. (See Answer, ¶¶ 27, 38, 50, 62, 75, 100).

1. JAX Poly-Guard FG-2: Counts I, VIII, IX and XI

In Counts I, VIII, IX and XI, Complainant alleges that **JAX Poly-Guard FG-2** is not registered under FIFRA. It is undisputed that that **JAX Poly-Guard FG-2** is not registered under FIFRA. (¶ 27 of the Answer, ¶ 8 of Joint Stips, page 12 of the Response to MAD).

2. JAX Halo-Guard FG-2: Counts II and III

In Counts II and III, Complainant alleges that **JAX Halo-Guard FG-2** is not registered under FIFRA. It is undisputed that **JAX Halo-Guard FG-2** is not registered

under FIFRA. (¶ 50 of the Answer, ¶ 14 of the Joint Stips, page 12 of the Response to MAD).

3. JAX Magna-Plate 78: Counts IV, V and VI

In Counts IV, V and VI, Complainant alleges that **JAX Magna-Plate 78** is not registered under FIFRA. It is undisputed that **JAX Magna-Plate 78** is not registered under FIFRA. (¶ 100 of the Answer, ¶ 29 of the Joint Stips, page 12 of the Response to MAD).

4. JAX Magna-Plate 74: Count VII

In Count VII, Complainant alleges that **JAX Magna-Plate 74** is not registered under FIFRA. It is undisputed that **JAX Magna-Plate 74** is not registered under FIFRA. (¶ 75 of the Answer, ¶ 20 of the Joint Stips, page 12 of the Response to MAD).

5. JAX Halo-Guard FG-LT: Count X

In Count X, Complainant alleges that **JAX Halo-Guard FG-LT** is not registered under FIFRA. It is undisputed that **JAX Halo-Guard FG-LT** is not registered under FIFRA. (¶ 62 of the Answer, ¶ 17 of the Joints Stips, page 12 of the Response to MAD)

D. The lubricants distributed or sold by Behnke are "pesticides" as defined by FIFRA

In each of the eleven counts, Complainant alleges that the lubricants that were distributed or sold were "pesticides" as defined by FIFRA. This is the only element of proof that Respondent has not admitted or stipulated to in the pleadings. However, the evidence in the record clearly demonstrates that each of the five lubricants in question are indeed pesticides under FIFRA. The U.S. EPA has met its burden and demonstrated by a preponderance of the evidence that **JAX Poly-Guard FG-2, JAX Halo-Guard FG-2, JAX Halo-Guard FG-LT, JAX Magna-Plate 74** and **JAX Magna-Plate 78** are

pesticides under FIFRA, and therefore were required to be registered under FIFRA at the time of each distribution or sale as identified in the Complaint.

Respondent argues that it is exempt from FIFRA for a number of statutory and regulatory reasons. However, the record is clear that Behnke does not fall under any exemption recognized under FIFRA for the lubricants in question.

1. Behnke's lubricants are not exempt from FIFRA under 40 C.F.R. Section 152.5(d)

Behnke first contends that it is not subject to FIFRA because its lubricants do not target "pests," as that term is defined under FIFRA and its implementing regulations. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.3, in pertinent part, define "pesticide" as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. Section 2(t) of FIFRA defines "pest," in pertinent part, as any form of virus, bacteria, or other microorganism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals). This definition is further qualified by the definition of "pests" found at 40 C.F.R. § 152.5(d) which, in pertinent part, states that an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is "any fungus, bacterium, virus, or other microorganisms, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs ... and cosmetics ...."

In order to determine if Behnke's lubricants target "pests" as defined under FIFRA, a number of questions must be answered.

a. Behnke's lubricants are targeting "pests"

The initial question is whether Respondent's lubricant products target (i.e., "are intended for preventing, destroying, repelling or mitigating") "pests" within the meaning of FIFRA. After a careful review of the documentary and testimonial evidence, it is clear that each of Behnke's lubricants targets "pests," as that term is defined in FIFRA. Each of the witnesses called by U.S. EPA testified as to the nature of Behnke's labeling, advertising and marketing claims associated with the lubricants in question. Behnke's advertising and marketing efforts consistently advertised that its lubricants were intended to mitigate, destroy or control microorganisms such as Listeria, E. coli and Salmonella. These microorganisms are bacteria, and are "pests" within the meaning of FIFRA. (See 40 C.F.R. §152.5(d), and April 1 Tr., at 0469-0475).

On March 31, 2008, Mr. Jeffrey Saatkamp of the WDA testified that he conducted an Internet search prior to inspecting the Behnke facility on August 3, 2006. He further testified that he found a number of advertising and marketing claims made by Behnke regarding its JAX lubricants containing antimicrobial technology, and that these claims specifically stated that the lubricants were intended to target harmful microorganisms such as Listeria, E. coli and Salmonella. (CX 1a, March 31 Tr., 0053-055).

On March 31, 2008, Mr. Joshua Rybicki of the Inventory Control Division of American testified on behalf of U.S. EPA. He testified that the American (Acme) facility began purchasing **JAX Poly-Guard FG-2, JAX Magna-Plate 74** and **JAX Magna-Plate 78** after meeting with one of Behnke's salespersons who introduced the JAX lubricants with Micronox antimicrobial technology to American. (CX 16, ¶¶ 19, 21-25, March 31 Tr., 0088-0089, 0108). He further testified that Behnke had informed him both

verbally and through its advertising and marketing literature that the lubricants are intended to target harmful bacteria such as Listeria, E. coli and Salmonella. (CX 8a, b, and c, CX 16, ¶¶ 14-15, March 31 Tr., 0088, 0096, 0122-0124).

On March 31, 2008, Mr. Terence Bonace, a Life Scientist at U.S. EPA, also testified on this matter. Mr. Bonace testified about numerous Internet searches relating to this case. He also testified that he had conducted a number of follow up investigations at Behnke's customer sites. He further testified that some of the advertising and marketing materials he found on the Internet and at these customers' sites regarding Behnke's JAX lubricants specifically identified the types of harmful bacteria the lubricants were intended to target, which included but were not limited to Listeria, E. coli and Salmonella. (CX 1,6a, b, c, 8, 8a, b, c, 9, 12, 12a, 13, March 31 Tr., 0142-0143, 0157-0167, and 0178-0179).

On April 1 and 2, 2008, two expert witnesses testified on behalf of U.S. EPA. The first expert witness was Mr. Dennis Edwards, Chief of the Regulatory Management Branch in the Antimicrobials Division of the Office of Pesticide Programs at U.S. EPA. Mr. Edwards was clearly established as an expert witness in the process and policies governing the registration of pesticides under FIFRA, and in interpreting and implementing such policies to determine when and under what circumstances such pesticides must be registered under FIFRA. Mr. Edwards possesses extensive knowledge and experience regarding the pesticide registration process (and in particular antimicrobial pesticide registration) and has implemented and applied the very policies and laws that are the subject of this case for over 30 years and many hundreds of times. Mr. Edwards' testimony was offered to assist in the Court's understanding of the facts of

this case in the context of U.S. EPA's policies, guidance and historical interpretation of FIFRA and its implementing regulations. (See April 1 Tr., 0236-0265).

Mr. Edwards testified in great detail regarding the labeling, advertising and marketing claims made by Behnke regarding its lubricants. He specifically noted that Behnke had identified a number of microorganisms that its lubricants are intended to target, including but not limited to Listeria, E. coli and Salmonella. (April 1 Tr., 0275-0288, 0321, 0432).

The final expert witness was Dr. Tajah Blackburn, who is employed by the U.S. EPA as an efficacy evaluation Team Leader in the Product Science Branch of the Antimicrobial Division of the Office of Pesticide Programs. (April 1 Tr., 0458). Dr. Blackburn holds a Ph.D. in Biomedical Sciences, with a concentration in Microbiology and Immunology. (April 1 Tr. 0449). Her area of specialty was enteric pathogens, microbes that live in the gastrointestinal tract of animals and humans. (April 1 Tr. 0449). Her studies covered bacteria such as Listeria, E. coli and Salmonella, three bacteria identified in Respondent' s advertising claims. (April 1 Tr. 0450-0453, 0469-0471, 0471-0473, 0473-0476). Dr. Blackburn has worked extensively in laboratories that analyzed microorganisms, and she was responsible for ensuring that food-borne pathogens were removed from food processing equipment. (April 1 Tr., 0453-0455). She has also performed between three-hundred and five-hundred efficacy evaluations of antimicrobial products, implementing guidelines for such efficacy evaluations which were developed under sound scientific principles to ensure that antimicrobial products are indeed as effective as advertised. (April 1 Tr. 0462-0464). Dr. Blackburn's testimony was offered to inform the Court about the nature of antimicrobial pesticides and public health

pesticidal claims, and to explain the necessity of regulating such pesticides. Dr. Blackburn's testimony was also offered to inform the Court of the characteristics and dangers of microorganisms such as Listeria, E. coli and Salmonella, and to discuss the importance of requiring efficacy testing when public health claims are made. (April 1 Tr., 0443-0444, 0449-0497).

Dr. Blackburn testified in some detail regarding Behnke's advertising and marketing claims associated with its JAX lubricants containing Micronox antimicrobial technology. Her testimony also demonstrates that Behnke specified that its lubricants target a number of bacteria, including but not limited to Listeria, E. coli and Salmonella. (April 1 and 2 Tr., 0497 - 0517).

The issue then is whether bacteria such as Listeria, E. coli and Salmonella are known pests deleterious to man. The regulation at 40 C.F.R. § 152.5(d) states that "an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is ... any fungus, bacterium, virus, or other microorganisms, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs ... and cosmetics..." Therefore, Listeria, E. coli and Salmonella, as bacteria, fit the definition of "pest" set forth above (except where such bacteria are "on or in living man or other living animals" or "on or in processed food or processed animal feed, beverages, drugs... or cosmetics"). In addition, U.S. EPA has historically considered such bacteria as pests within the meaning of FIFRA. Mr. Edwards testified that bacteria such as Listeria, E. coli and Salmonella are considered pests as defined in FIFRA:

Q. And can you tell the Court what an antimicrobial pesticide is?
A. An antimicrobial pesticide is an application for a pesticide product that's going to be

applied to an inanimate surface to control microorganisms.
Q. And what are public health antimicrobial pesticides?
A. Public health pesticides, antimicrobial pesticides, are pesticide products that are intended to control pests that are infectious or pathogenic to man.
0240
Q. Can you give an example?
A. E.coli, Listeria, Salmonella.
(April 1 Tr., 0239 - 0240).
0432
Q. Okay. Is E.coli a pest?
A. Yes, E.coli is a pest.
Q. How about Salmonella?
A. Salmonella is a pest.
Q. How about Listeria?
A. And Listeria.
Q. How about references to gram-positive and gram-negative, would that be pests as well?
A. Yes.
Q. Is there anything else on the language that you reviewed that I have missed that --
A. Well, mold is a pest. Yeast would be considered a pest.
Q. Yes. Okay. Anything else that I missed?
A. I'd have to go back and look, but I -- you know, I think they reference bacteria, not just gram-positive and negative.
Q. Yes, they do.
A. But just bacteria in general. That would be a pest.

(April 1 Tr., 0432). See also Dr. Blackburn's testimony. (April 1 Tr., 0450-0474).

This issue is further clarified in the case law. In *In the Matter of Microban Products Company*, 1998 EPA ALJ LEXIS 47 (June 29, 1998), the Administrative Law Judge issued an order reaffirming his April 3, 1998, Order which had taken "judicial notice of the fact that E. coli [Escherichia coli], Salmonella, Staph. [Staphylococci] are widely recognized as microorganisms infectious to man." Other Courts have consistently found that claims such as those made by Behnke in association with all of the **JAX** products that are the subject of the Complaint are pesticidal claims and thus are pesticides requiring registration under FIFRA. See *In Re Microban Products Company*, 11 E.A.D. 425 (EAB 2004) *(Microban II), In the Matter of Microban Products Company*, 1998

EPA ALJ LEXIS 135 (September 18, 1998) *(Microban I)*; *In the Matter of Pacific International Group, Inc.*, 1999 EPA ALJ LEXIS 27 (June 27, 1999); and *In the Matter of William E. Comley, Inc., a/k/a WECCO and Belach Tek, Inc., d/b/a/ TEK*, 2003 PA ALJ LEXIS 7 (January 31, 2003).

b. Behnke specifies where its lubricants are intended to target "pests"

Having established that Behnke's advertising and marketing materials (both in print and on the Internet), specifically state that the lubricants are intended to target disease-causing bacteria that are known pests, such as Listeria, E. coli and Salmonella, the next question addressed is where the JAX lubricants containing Micronox antimicrobial technology are intended to control the pests.

i. Behnke's lubricants are not intended to target "pests" "in" " processed foods"

The record is devoid of any documentary or testimonial evidence to support Behnke's assertion that the Micronox technology was intended to target pests "in or on processed foods." First, there is no evidence even suggesting that the lubricants were intended to be placed in processed food. In fact, the testimony and the record show something quite to the contrary. Mr. Rybicki of American testified that Behnke's salesperson had never told American that it should list the lubricants in question as ingredients in its food products.

Q. Okay. Has Behnke ever told you to list the -- Has Behnke ever told Acme to list the lubricant as an ingredient in their food products?
A. I was never told to.
Q. Would that have been a problem if Behnke told you that?
A. Yes. I would -- Yeah. Yeah.

(March 31 Tr., 0119).

The same line of questioning was asked of Behnke's own witnesses. On cross examination, Eric Peter, despite his evasive testimony, admitted that it was not Behnke's intent to have the lubricant added into any processed foods, nor would the Food and Drug Administration (FDA) allow Behnke to add the lubricant (which is only allowed to make incidental contact with food) into any processed food:

Q. Okay. Do you tell any of your salespeople to market your products by telling them that – let me restate that. Do you train your salespeople with respect to Micronox technology?
A. Not personally.
Q. But ultimately you're responsible for it, correct?
A. Yes.
Q. Do you know if in the training they're told to tell their customers that the lubricant should be listed as an ingredient because it's going to be in food?
A. No.
Q. You don't know or --
A. No.
Q. -- they don't?
A. No.
0718
Q. Do they tell your customers to list the --
A. That wasn't your question.
Q. All right. Well, I'll ask another one. Do your salespeople tell your customers to list the lubricant as an ingredient in the processed food?
A. I would think it would be likely they would not.
Q. Okay. But -- okay. In fact, the FDA regulations don't allow Behnke to add the lubricants into the food directly; do they?
A. Correct.
Q. And the lubricants with Micronox technology are not designed to be applied onto or added into the food under FDA, correct?
A. Correct.
Q. Do you know if any of your customers actually list them as ingredients in their food?
A. I sincerely doubt it.
Q. Okay.
MR. MCILNAY: Her question was, do you know.
THE WITNESS: I do not know.
BY MS. O'MEARA:
Q. Do you know if anybody lists them on the nutrition labels?
A. I do not know.
0719
Q. Do you doubt it?
A. I doubt it.

Q. In fact, the lubricants are not actually intended to become a component of the food, correct?
A. Not intended, but they do.
Q. Trace amounts of it, correct?
A. Sometimes not trace amounts.
Q. Okay. But that's not the intent, correct?
A. That's not the intent.
Q. Thank you. And the lubricants aren't intended to have any sort of technical effect on food, are they?
A. No.
Q. And they're not intended to actually get into the food, correct?
A. Not intended to.
Q. Okay. None of your advertising or marketing literature advises your potential customers to list the lubricants as food, as ingredients in food, correct?
A. Correct.
Q. And none of your advertising or marketing or labeling literature tells your potential customers that deadly organisms like E. coli, Salmonella and Listeria will be killed upon contact on food, right, when the Micronox hits it?
A. I do not believe currently it should say any of that.

(April 2 Tr., 0718-0720). See also Mr. Paquette's testimony. (April 3 Tr., 0806-0809).

ii. Behnke's lubricants are not intended to target "pests" "on" " processed foods"

Just as importantly, the record is devoid of any evidence supporting Behnke's assertion that the lubricants were intended to be placed on processed food. Therefore, the Micronox antimicrobial technology of the lubricant products cannot be said to target microorganisms on (or in) processed foods. Mr. Rybicki testified that he was never told that the lubricants should be placed on the meat to achieve its desired antimicrobial effect:

Q. Did the Behnke salesperson ever tell you that the lubricant should be applied directly on meat?
A. No.
Q. Did he ever tell you that the lubricant had to touch the meat before it began to work?
A. That was not my understanding, no.

(March 31 Tr., 0084-0084). In fact, Mr. Rybicki even testified that if lubricant got on the meat in the facility, the plant personnel would do everything possible to cut the contaminated part of the meat out and discard it:

Q. Okay. And you were asked some questions about the lubricant in or around food. I'm going to ask you a couple questions about that. Can you tell us what Acme's protocol is if any lubricant gets on the meat that is being handled?
A. The meat is retained, shown to a USDA inspector. Then they will cut out, like, the area or part that the oil is on, and then they will inspect it again. And then the USDA will either say yes or no if we can put it back into production or if we have to condemn the carcass or piece of meat.

(March 31 Tr., 0118-0119).

Mr. Peter also testified that the lubricants are not intended to be placed directly in food. (April 2 Tr., 0718). Behnke did not present any evidence to support its implication that the lubricants are "on or in processed food" as that term is used in FIFRA. Mr. Peter could not recall any such evidence:

Q. Do you have any labels in the record that show that there were, at any time, any advertising that stated that the lubricant with the Micronox antimicrobial technology was intended to protect any food, any processed food?
A. I don't know.
Q. You don't know if there is any such label?
A. I don't know.

(April 2 Tr., 0699). Further, one of Behnke's distributors, Mr. Larry Cooper, testified that, at the food processing plant where he had worked, lubricating grease was considered undesirable on the food itself, and that food on which such grease had fallen was removed from production and discarded:

Q. Okay. Now, you testified that when grease got on a product, it was a problem --
A. Yes.
Q. -- is that correct?
A. (Witness nods head.)
Q. And as a maintenance coordinator, you had to find out whose fault it was; is that correct?
A. That is correct.

0852
Q. And that was because you didn't want to get any of the grease on the food?
A. That's correct.
Q. Okay. Forgive me if some of these questions silly. It is what it is, but -- You didn't keep the food that got grease on it, did you?
A. Oh, no.

(April 3 Tr., 0851-0852). Clearly, the lubricants were never intended to be placed on or in processed food.

iii. Behnke explicitly claims that its lubricants are intended to target "pests" in the lubricant itself

On the other hand, the record contains ample evidence that the Micronox antimicrobial technology is in the lubricant itself and is intended to protect the lubricant from pests such as Listeria, E. coli and Salmonella. Behnke made claims throughout its advertising and marketing materials that the lubricants containing Micronox antimicrobial technology are intended to be protected from harmful microorganisms such as Listeria, E. coli and Salmonella. Behnke even advertised the results of some purportedly independent testing that claimed to show the number of bacteria in its lubricants as compared to its competitors. (see e.g., CX 8c, at EPA 0260.) Clearly, the fact that Behnke tested the lubricants themselves for bacteria levels rather than testing the processed food is further evidence that Behnke intended the Micronox antimicrobial technology to protect the lubricant and to avoid cross contamination, rather than to kill or control microorganisms on the processed food in the facility. (CX 1, at EPA-0021, EPA-0023, EPA-0025; CX 6a, at EPA-0104; CX 6c, at EPA-0152, EPA-0153, EPA-0154, EPA-0156, CX 8, at EPA-0186, EPA-0188; CX 8a, at EPA-0208, EPA-0210, EPA-0212, CX 12, at EPA-0303, EPA-0305, EPA-0308, EPA-0312; CX 36, at EPA-0751; CX 46, at EPA-0890 and EPA-0891).

In addition, many of the witnesses also testified regarding this issue. Mr. Josh Rybicki testified that he understood the Micronox antimicrobial technology to control bacteria in the lubricant itself in an effort to minimize cross contamination to the food in the facility:

Q. And did he indicate to you where the bacteria would be inhibited as a result of the Micronox technology?
A. Within the grease, my understanding of their conversation when we stopped by.
0084

(March 31 Tr., 0083-0084).

Q. What is your understanding of how the Micronox antimicrobial technology in the lubricant was going to keep bacteria counts down?
A. My understanding of it was when we have the grease and the oils and we're using them in our production facility, the grease is either put on a bearing or the lubricant, like, the oils are sprayed on the chains, on overhead chains or inside gear boxes. And my understanding was that -- and a lot of our understanding, not just myself but some other colleagues when I had presented this information to them, was that the oil itself is a point of where the bacteria would not -- would be inhibited.

(March 31 Tr., 0085).

Q. Now, these three pieces of literature that we just talked about, 8A, 8B, and 8C, what did this literature in its totality tell you about JAX Micronox antimicrobial technology, Mr. Rybicki?
A. More so this last one here, I mean that specifically outlines the Micronox technology. It told me that if I was to use this product in my production facility, that it would help inhibit the growth of the bacteria within the grease or the oils and anyplace that -- on any of the machinery that we use this on.

(March 31 Tr., 0095).

In addition to the many claims made by Behnke in its advertising and marketing materials that demonstrate that Behnke added Micronox antimicrobial technology into the lubricants to preserve the lubricants themselves, Behnke's own pleadings in the lawsuit it brought against NSF International demonstrate this intent. (CX 36, EPA 0755). Behnke even stated in its Answer to the Complaint in the instant matter that the antimicrobial

properties of its lubricant products are intended to protect the lubricants and the equipment to which the lubricants are applied. (Answer at Affirmative Defense 6.)

Additionally, Mr. Peter admitted to his understanding that the Micronox technology works by killing bacteria in the lubricant itself, and his testimony and declaration demonstrate that Behnke's advertising and marketing efforts made claims that Behnke intended the Micronox antimicrobial technology to protect the lubricant itself from harmful bacteria such as Listeria, E. coli and Salmonella:

Q. So would the Micronox technology kill the E. coli, the Salmonella, or control it, the E. Coli, Salmonella or Listeria, when the bacteria gets into the lubricant, because that's where the technology is?
A. Would it -- yes.
Q. So kill it on contact in the lubricant, correct?
A. I don't know the capabilities of, on contact, but --
Q. It would kill it in the lubricant, correct?
A. Eventually it would not survive in the lubricant either.
Q. Okay. So that when the lubricant drips down onto the food, for example, it doesn't have a colony growth of these E. coli, Salmonella and Listeria bacteria in it, correct?
A. Correct.
Q. You said that you -- that the Micronox technology was not in the lubricant to preserve itself; is that correct?
A. Correct.
0715
Q. But some of your advertising, you will admit, says that it is in there to preserve itself, correct?
A. Correct.
Q. Would you also admit that in the NSF lawsuit -- well, let's turn to it. It's again Complainant's Exhibit 36. I'd ask you to turn to Page 2 of that which is EPA 751. EPA 751. Could you read into the record, please, starting, The Micronox product, which is the third full sentence, please.
MR. MCILNAY: Of which paragraph?
MS. O'MEARA: Paragraph 5 on page EPA 0751.
THE WITNESS: The Micronox product has antimicrobial properties which no competing product contain. These properties extend the useful lives of the food-grade lubricants containing Micronox. It does this by retarding bacterial growth in the lubricant, which bacterial growth otherwise would degrade the lubricants and make them potential harbors for bacteria.
0716
BY MS. O'MEARA:
Q. Thank you. So is that not correct?

A. That's not correct.
Q. And your advertising isn't correct either, correct, that says that the lubricant is there to preserve itself -- I mean, sorry -- the Micronox in the lubricant is there to preserve the lubricant itself?
A. It's incorrect that the microbes will degrade the lubricant.
Q. Okay. I understand that. Is it correct that the Micronox technology was intended to kill the E. coli and Salmonella and Listeria in the lubricants?
A. It will do that, but that's not what it was intended for.
Q. Is it correct that some of your advertising literature says that it will do that?
A. Yes.

(April 2 Tr., 0714-0716). See also testimony of Troy Paquette (April 3 Tr., 0807-0809).

Despite Mr. Peter's efforts to tell the Court that Behnke did not truly intend the Micronox technology to preserve the lubricant itself, Mr. Peter cannot escape his own testimony, the advertising and marketing literature in the record, the statements made by Behnke in the complaint it filed against NSF in federal court, and the statements made by Behnke in the pleadings in the matter before this Court (affirmative defense 6 in its Answer). None of these various statements ever suggested that the lubricants or the Micronox technology were intended to be applied "on or in processed food." To the contrary, Behnke's numerous claims all indicate that the antimicrobial effect of Micronox was to take place within the lubricant itself.

iv. Behnke implies that its lubricants are intended to target "pests" on the equipment that is lubricated

Behnke also made antimicrobial claims in its advertising and marketing materials that imply that the lubricants protect the equipment from harmful microorganisms. (CX 1a, at EPA-0057; CX 6a, at EPA-0104 and EPA-0116). Mr. Rybicki touched on this issue in his testimony as well. (March 31 Tr., 0095).

v. Behnke fails to specify exactly where the lubricants containing Micronox antimicrobial technology are intended to target "pests"

The evidence also shows that there are many instances where Behnke advertised and marketed its products without specifying where the Micronox antimicrobial technology was intended to target microorganisms such as Listeria, E. coli and Salmonella. (CX 1, EPA-0021 and EPA-0025; CX 1a, at EPA-0057 and EPA-0058; CX 3, at EPA-0061, EPA-0062, EPA-00 66 and EPA-0071; CX 4, at EPA-0072, EPA-0074, EPA-0077 and EPA-0078; CX 5, at EPA-0082; CX 6a, at EPA-0102, EPA-0106, EPA-0110, EPA-0112, EPA-0113 and EPA-0118; CX 6b, at EPA-0123, CX 6c, at EPA-0141, EPA-0155 and EPA-0164; CX 8, at EPA-0184, EPA-0186, EPA-0187 and EPA-0188; CX 8a, at EPA-0208, EPA-0209; CX 8b, at EPA-0242, EPA-0243, EPA-0249; CX 8c, at EPA-0253, EPA-0256, EPA-0257, EPA-0259, EPA-0270, EPA-0271; CX 9, at EPA-0279, EPA-0283, EPA-0285; CX 10, at EPA-0291; CX 11, at EPA-0297, EPA-0298; CX 12, at EPA-0305, EPA-0310, EPA-0312; CX 13, at EPA-0324; CX 15, at EPA-0353; CX 35, at EPA-0726, EPA-0727, EPA-0730, EPA-0732, EPA-0733, EPA-0735; CX 46, at EPA-0880, EPA-0882 and EPA-0890). The seminal document explaining the Micronox technology, the December 2001 "Technology Focus" informational packet which Behnke had supplied to American Foods (CX 8c), describes in great detail how the antimicrobial properties of the Micronox technology were tested by analyzing the microbial content of the lubricants themselves (Magna-Plate 78, Conveyor Glide, Poly-Guard FG 2). (e.g., CX 8c, at EPA 0260, EPA 0262, EPA 0270, EPA 0271 and EPA 0272). No documents presented by either party to this action discuss any testing of the microbial content of any *food* to which lubricants containing Micronox were added. Respondent's unsubstantiated

assertion that the Micronox technology targets microorganisms "on or in processed food" is devoid of evidentiary support, and is contradicted by the evidence in the record. Further, Behnke has failed to offer any historical records suggesting that the Micronox was intended to kill or mitigate microbes "on or in processed food." It is clear that Respondent's argument was conceived after-the-fact, for the purpose of creating an unsubstantiated defense to FIFRA liability, without regard to the statements which Behnke actually had made concerning the Micronox technology outside of the context of the instant litigation.

vi. Given the opportunity, Behnke would sell its lubricants to customers that are not handling "processed foods"

Behnke also maintains that its products are only sold to the food processing industry, a market consisting of "sophisticated buyers." (Behnke's Response to MAD, at 26). However, the evidence does not support that assertion. Furthermore, Behnke's own president admitted on cross examination that he would sell the lubricants to markets outside of the food processing industry if given an opportunity. He also admitted that he has no control over how an end user may utilize Behnke's lubricants. Therefore, it is entirely possible that the lubricants could be and are being used in settings where food is not even being handled, or in settings where the food that is being handled is not considered "processed food" under the interpretation of either FDA or U.S. EPA[17].

[17] The FDA and U.S. EPA have historically drawn a distinction between "processed food" and "raw agricultural commodities," which are not considered processed foods because they have not yet gone through any processing. The distinction is discussed in CX 20, Section 7 (at EPA 0541-43), and specifically states that "shelling of nuts" does not constitute processing.

The potential for Behnke's products to be purchased by members of any type of industry was made clear by Mr. Peter's own testimony:

A. I'd like to see my market open up for these lubricants.
Q. Okay. And the lubricants that are food-grade; is that correct?
A. Yes. I'm not discriminatory, though. I'll have it open up for any of these lubricants.
Q. I can appreciate that, because you are a business, and you're in the business of making money, correct?
A. Right.
0643
Q. Okay. And you also said that you couldn't see a use for these food-grade lubricants out of a food processing facility; is that correct?
A. I can't perceive a use why anyone would be motivated to use them outside of a food processing facility.
Q. Okay. If someone was, though, would you sell it to them?
A. I have little or no control over where the end user uses these products, so I would.
Q. You have little or no control where it's used. So it could be used in a nonfood form, correct?
A. In theory.
Q. In theory. Okay. Let me give you a hypothetical. Let's say Hasbro Toy Company comes to you and wants to have you enter into a $1 million contract for your lubricants, okay, because they believe that this lubricant is falling onto those toys, and those toys are being chewed by children, and it will safeguard the children. Would you engage in that contract with them?
A. It's a legitimate concern.
Q. Okay. Would you engage in that contract with them? Would you then sell that lubricant, that food-grade lubricant? They're willing to take that risk to safeguard children. Would you sell that food-grade lubricant to Hasbro?
A. Yes, I would, sure.
0644
Q. Okay. And they would use it in a nonfood form, and you couldn't control that; isn't that correct?
A. Correct.
Q. Okay. And let me give you another example. You said that they don't get sold in the retail market. I bet you'd like to open up the retail market; wouldn't you?
A. No. I have no interest in retail.
Q. You have no interest in selling your product in another market?
A. No.
Q. Okay.
A. Not retail.
Q. Let me give you a hypothetical. Let's say pet stores want to come to you and buy that product because the wheels on their hamster wheels are squeaking, and the hamsters are licking that wheel. And this lubricant is food-grade. Would you sell it to them?
A. I'll sell it to whoever wants to buy it.
0645

Q. Okay. All right.
A. If they pay their bill.
Q. If they pay the bill. Okay. Would you consider a toy a food?
A. Unless it's an edible toy, I wouldn't.
Q. Okay. Just a plastic toy, would you consider that food?
A. I've never eaten one.
Q. Okay. Good. How about this pen, is this food?
A. I don't consider a pen food, no.
Q. Okay. Let me give you another hypothetical. This is a Skilcraft. If they came to you and said, we want to use these in our manufacturing facilities because we think the lubricant is falling onto the production line, and we'd rather have a food-grade lubricant instead. Because I tend to chew my pens when I get nervous, so I might consume it, and someone else might. Would you sell it to them?
A. Certainly.

(April 2 Tr., 0642-0645). Later in his testimony, Mr. Peter admitted that he would sell his company's lubricants to customers who process raw agricultural commodities, which both U.S. EPA and the FDA consider to fall outside the definition of "processed food."

BY MS. O'MEARA:
Q. Now, you said earlier that your lubricants with the Micronox technology were intended to target food pathogens; is that correct?
A. Correct.
Q. Are you still stating today that they're intended to target them on food?
A. Correct.
Q. Only on processed food?
A. Only on processed food? That's correct.
Q. Could it be on raw food as well, raw agricultural commodities as well?
MR. MCILNAY: Objection, Your Honor, to the extent that that calls for a legal conclusion. As Your Honor and Counsel --
MS. O'MEARA: I'll restate it.
MR. MCILNAY: RAC's are a term of art.
0711
BY MS. O'MEARA:
Q. Could it be targeting, let's just say, fruit that hasn't been washed, organisms on fruit that hasn't been washed?
A. I don't know how it would get on fruit that hasn't been washed.
Q. How about nuts, we talked about nuts. Could it be targeting nuts that are still in their shell, going through a conveyor belt with a lubrication above?
A. I don't know what the pathogens would be on the nuts.
Q. But you would sell that lubricant to a facility that perhaps would be handling that scenario that I just described, correct?
A. Yes.

(April 2 Tr., 0710-0711). Therefore, it is apparent that Behnke's lubricant products may very well be purchased and used by companies whose facilities are not involved with processing foods.

c. Behnke's lubricants are not "processed foods"

Behnke has even suggested that its lubricants themselves can be considered "processed foods." (See Response to MAD, page 23). However, the evidence is overwhelming that Behnke's lubricants are not in and of themselves "processed foods." The labeling, advertising and marketing literature and the testimony offered at hearing make it clear that the lubricants are designed to be placed on equipment, including gear boxes and inside bearing cavities, (e.g., CX 8, at EPA 0186 ("For years, Magna-Plate 78 has protected enclosed spur and bevel gears..."), CX 8c, at EPA 0257 ("lubrication of high-speed seaming rolls") and EPA 0270 ("Poly-Guard FG2 introduced to the bearing")), and are not designed to be intentionally eaten. This was further bolstered by Mr. Peter's testimony.

Q. Are you stating today -- I just want to clarify because I can get rid of a bunch of questions if I get the answer I'm looking for -- that the lubricant is not a food, a processed food?
A. No.
Q. I'm sorry. Let me clarify the question. Is the lubricant, are you claiming that the lubricant is a processed food?
A. That lubricant itself is a processed food?
0712
Q. Yes.
A. No.
Q. So you wouldn't eat the lubricant, correct?
A. Not intentionally.
Q. Not intentionally. You wouldn't put it on a cracker and eat it, would you?
A. Not intentionally.

(April 2 Tr., 0711-0712).

Finally, U.S. EPA's expert, Mr. Edwards, also offered his opinion on this matter at hearing.

Q. Is it your opinion that the lubricants are food, processed food?
A. No. They're intended to be lubricants. That's the whole -- I mean, if you look at most of the literature, that's was probably 60, 70 percent of the description provided.

(April 1, Tr., 0332). See also CX 19 (63 Fed. Reg. 54533 (October 9, 1998)), at EPA 0523 ("EPA has historically interpreted the words 'processed food' ... as they are commonly understood--food that has undergone processing and is intended to be consumed immediately or after some further processing or preparation. Because the commonly understood meaning of these terms applies to edible food articles, EPA has not considered food-contact items ... to be 'processed food' within the meaning of that term in FIFRA and EPA's implementing regulations. Thus, EPA has regarded any antimicrobial substance used in or on paper, paperboard, or other food-contact items as a "pesticide" under FIFRA.")). Thus, it is clear that the lubricants cannot be considered as "processed food" under FIFRA.

d. 40 C.F.R. § 152.5(d) does not apply merely because the pests being targeted originate from food

In Respondent's affirmative defense 7, Behnke argues that microorganisms which originate from "processed foods" are exempt under the definition of "pest" at 40 CFR § 152.5(d). In its defense, it essentially implies that if the microorganism in question originates from a "processed food," U.S. EPA loses jurisdiction over the product under FIFRA. Behnke failed to offer any evidence during hearing to support such an assertion, nor could Behnke offer any legal authority supporting this argument.

It is important to note first that Behnke is incorrect in making an assumption that the only origin of deleterious microorganisms such as Listeria, E. coli and Salmonella in

a food processing facility is the processed food itself. U.S. EPA's expert witness, Dr. Blackburn, testified as to the other possible origins of such microorganisms at hearing:

Q. Okay. How do bacteria such as Salmonella, E. coli, and Listeria first enter a facility where animals are slaughtered and processed?
A. The most common route of entry would be the actual animal. Cattle in particular are surrounded by their waste, their feces. And they can track their feces, or they track their feces into the establishment. The fecal matter is on their hide, on their hooves, on their tails. They can pretty much be covered in it, macroscopically as well as microscopically. Also, the workers of the facilities can bring these organisms into the plant as well.
0477
Q. Okay. And how would workers bring the organisms into the plant?
A. They can bring these organisms in by having contact with animals before they enter the plant, as well as not following proper hygiene practices when they go to the restroom, for an example.

(April 1 Tr., 0476-0477). Dr. Blackburn further testified that equipment in a slaughterhouse can be contaminated by bacteria through aerosolization, a process in which bacteria from fecal matter are transported through the air in water droplets forming a vapor:

Q Now, Dr. Blackburn, are there ways that equipment can become contaminated with these bacteria other than by direct contact either with people or with the animals to be slaughtered?
A Yes.
Q And how could the equipment be contaminated in this manner?
A The equipment can become contaminated via aerosolization of the microbes via blood splatter, via fecal splatter.
Q Okay. What does the term aerosolization mean?
A Aerosolization is when these particles, or the fecal matter and the microbes contained within the fecal matter, can be transferred or carried in the air to a lesser degree, or to a greater degree, on water vapors, or when particles are moved, shifted, and it generates some air volume, a flow of air, then the particles can be
0479
aerosolized at that time.

Q Okay. And can each of these three bacteria we've been discussing, Listeria, Salmonella, and E. coli become aerosolized in this way?
A Yes, they can.
Q Okay. Now, within the water vapor droplets, will they usually be in organic matter?
A Yes.
Q And will the bacteria be in the organic matter?
A Yes.
Q In a slaughterhouse, what is the most prevalent or most common form of organic matter that will be found in water vapor droplets?
A I would say feces, from my observation, because the volume of waste there is immeasurable. It's copious, it's ubiquitous, it's everywhere. And that would be the source.
Q Now, in what kind of organic matter will Listeria, E. coli, and Salmonella be most concentrated?
A In fecal matter.

(April 1 Tr., 0478-0479).

Dr. Blackburn's testimony demonstrates that microorgaisms such as Listeria, E. coli and Salmonella can be transferred to food processing equipment by means other than contact between such equipment and the animal parts being processed. In addition, her testimony underscores the fact that the organic matter most commonly serving as a source of these deadly bacteria is fecal matter, a substance that cannot be confused with "processed food."

The fact that bacteria such as Listeria, E. coli and Salmonella do not always originate from "processed food" is further supported by Dr. Blackburn's testimony that vegetables become contaminated with these bacteria through contamination from external sources, and that none of these bacteria exist naturally inside a vegetable.

22 Q Let's talk briefly about vegetable processing.
23 How can a vegetable become contaminated with the
24 three bacteria we've been discussing?
25 A They can become contaminated via manure that's

0480

used to fertilize the actual plants, from using untreated water, from cross-contamination, that is the transfer of microbes from the individual that's handling those microbes to the actual vegetable or fruits, etc.

Q Do any of these three bacteria exist naturally inside a vegetable?

A No.

(April 1 Tr., 0479-0480). Dr. Blackburn also testified that, when she worked for the Nestle/Earthgrains laboratory as a microbiologist, one of the company's concerns was contamination from bacteria such as Listeria, E. coli and Salmonella (April 1 Tr., 0454-0455). She also testified that none of these bacteria existed naturally in the product manufactured at that facility (cookie dough), and that the sources of contamination would be other entities from which these microorganisms were transferred (April 1 Tr., 0455). Hence, Behnke's unsupported assertion that the microorganisms targeted by its Micronox antimicrobial technology must always be assumed to have originated from "processed food" was contradicted at hearing by the expert testimony of Dr. Blackburn.

Secondly, despite the fact that it is impossible to determine the origin of such deleterious microorganisms in any given situation, Behnke is mistaken in stating that microorganisms which originate from "processed foods" (such as the bacteria to which Behnke's lubricants are often exposed during animal slaughtering operations) are exempt from the definition of "pest" at 40 C.F.R. § 152.5(d). U.S. EPA requires the registration of pesticidal products that prevent, destroy, repel or mitigate microorganisms such as Listeria, E. coli and Salmonella. Specifically, U.S. EPA requires the registration of countless sanitizers, disinfectants and sterilants used in meat processing plants to clean the floors, walls, work surfaces and equipment handling processed meats, even though

the pests that these products are designed to address may originate from the processed meats at such facilities. (April 1 Tr., 0261-0262). Under Respondent's interpretation of the definition of "pest," all of these products would be exempt from registration because they would be preventing, destroying, repelling or mitigating microorganisms that "originated" from the processed meats in such facilities. Accepting such an interpretation of the FIFRA statute and regulations would result in an enormous and unintended loophole in the FIFRA registration process. The resulting loophole would obviate the need for the registration of all products making food borne public health claims, and would not serve to effectuate the purpose of FIFRA and its implementing regulations. *See In re Sporicidin International, Inc.*, 3 E.A.D. 589, 604 (CJO 1991) (FIFRA is a remedial statute and, as such, "should be construed liberally so as to effectuate its purposes.").

Federal Courts have also addressed the meaning of "on or in" in the context of FIFRA. In *Kenepp v. American Edwards Laboratories*, 859 F. Supp. 809, at 816, n. 4 (E.D. PA 1994), the district court for the Eastern District of Pennsylvania rejected the argument that, because an antimicrobial product targeted the Human Immunodeficiency Virus, it was not a pesticide under FIFRA. The court held that "[t]he defendants' products are designed in part to kill Human Immunodeficiency Virus (Type 1) on hospital instruments, and are not for use 'on or in living man.' Accordingly, the court finds that the defendants' products are 'pesticides' within the meaning of FIFRA." In other words, simply because the targeted microorganism originates from a human being does not mean that that microorganism is always considered "on or in living man." Therefore, when the microorganism contaminates an object such as a hospital instrument,

the microorganism is no longer "on or in" the human (i.e., it is no longer "on or in living man"), and a sanitizer intended to kill such microorganisms when they are on hospital instruments is a pesticide requiring registration under FIFRA. By logical extension of this sound judicial reasoning, if a microorganism originates from processed meat, but comes to contaminate food processing equipment or the lubricant on that equipment, that microorganism is no longer "on or in processed food," and an antimicrobial product that targets that microorganism on the equipment (or in the lubricant on that equipment) is a pesticide under FIFRA.

In the instant matter, the antimicrobial properties of Behnke's lubricant products are not intended to kill or mitigate bacteria or other microorganisms while such microbes are on the processed food itself, and Behnke has neither advertised otherwise nor provided any evidence suggesting otherwise. Rather, the antimicrobial properties of Behnke's lubricants are intended to function in the lubricant itself, while the lubricant is on or in the equipment at a customer's plant. (E.g. CX 8c, at EPA 0257 and 0259).

Further, U.S. EPA's expert, Mr. Edwards, offered his opinion on this matter in the context of the facts relating to the Behnke lubricants.

Q. Mr. Edwards, can you tell us what your opinion is as to whether the Respondent's antimicrobial lubricants, all five of them that we've been discussing, are only targeting microorganisms coming from or -- coming from on or in processed food? Would that then exempt them?

A. No, it would not exempt them. The claims vary all over the place in a sense. I mean, in one place they talk about that the Micronox is intended to preserve the product. In another place it's suggested that it could substitute as a sanitizer. In other places it's very vague, and it doesn't specify why the Micronox is in the product. It talks about enhanced antibacterial protection, but it doesn't really specify where. It talks about, in a sense, throughout the plant, so it could be from any. But for us to apply that exemption, for me to consider that these aren't pesticide products, that they are regulated exclusively by FDA, I would need to see some directions that talk specifically about the fact that they are applied directly to processed food.

0332

Q. Okay.
A. Not through an incidental -- possibly an incidental contact.

(April 1 Tr., 0331-0332).

e. *The plain language of 40 C.F.R. § 152.5(d) is clear*

The plain language of 40 C.F.R. § 152.5(d) could not be any clearer: the exemption applies when the product in question is targeting "pests," as that term is defined under FIFRA, *on* or *in* processed food. The plain meaning of these words demonstrates that the exemption applies only to products that are directly added to or placed onto the food to kill or mitigate microorganisms. Behnke has not presented any evidence to this Court suggesting that its lubricants containing the Micronox antimicrobial technology target pests on or in processed food in this manner.

Historically, U.S. EPA has interpreted the "on or in processed food" exemption in a manner consistent with the regulatory language. U.S. EPA discusses the "on or in processed food" exemption in its *"Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances,"* 63 Fed. Reg. 54533 (October 9, 1998), which was jointly issued by the FDA and U.S. EPA and states:

Further, EPA has broadened this statutory exclusion in its FIFRA regulations at 40 CFR 152.5(d). Specifically, under this rule, an organism is not considered a "pest" if it is a "fungus, bacterium, virus, or other microorganisms [sic] . . . on or in processed food or processed animal feed, beverages, drugs, . . . or cosmetics . . . ." In applying this exclusion, EPA has historically interpreted the words "processed food" and "processed animal feed" as they are commonly understood--food that has undergone processing and is intended to be consumed immediately or after some further processing or preparation.

Because the commonly understood meaning of these terms applies to edible food articles, EPA has not considered food-contact items (such as paperboard and ceramic ware) to be "processed food'" within the meaning of that term in FIFRA and EPA's

implementing regulations. Thus, EPA has regarded any antimicrobial substance used in or on paper, paperboard, or other food- contact items as a "pesticide" under FIFRA.

In the footnote, this document also states:

The discussion in the paragraph above, however, does not purport to interpret the FFDCA definition, but rather to address the meaning of the terms "processed food" and "processed animal feed" used in FIFRA and EPA's implementing regulations.

(CX 19, at EPA 0523). Thus, for an antimicrobial product to be exempt from FIFRA regulation by virtue of its targeting only microorganisms that are "on or in processed food," the antimicrobial product would have to be intended for application directly onto "food that has undergone processing and is intended to be consumed immediately or after some further processing or preparation" – i.e., "edible food articles." As pointed out above, the evidence clearly demonstrates that none of Behnke's lubricants (nor the Micronox antimicrobial technology in the lubricants) are intended to be applied directly to food. Therefore, Behnke cannot avail itself of this exemption to FIFRA regulation.

The Label Review Manual (LRM) also speaks to this issue and states:

Antimicrobial products used solely in processed foods or feeds, in beverages, or in pharmaceuticals. Cracking, milling grinding and other process that cause the physical changes in the commodity are methods that meet the definition of "processed." Substances used in these processes against microbes in or on the processed food are not pesticides under FIFRA...

Products that are not intended to prevent, destroy, repel or mitigate a pest, or to defoliate desiccate, or regulate growth of plants are not considered to be pesticides. Some of these products may appear to be pesticides, but are not considered as such unless pesticidal claims are made on their labeling or in connection with their sale and distribution.

(CX 50, EPA 0924).

This issue is further discussed in guidance issued by the FDA, entitled "Antimicrobial Food Additives – Guidance," which states that "FDA and EPA have agreed that the following activities constitute processing and that any food subjected to

these activities becomes a *"processed food,"* (within the meaning of that term in 40 CFR 152.5): canning, freezing, cooking, pasteurization or homogenization, irradiation, milling, grinding, chopping, slicing, cutting, or peeling." (CX 20, at EPA 0542).

Finally, Mr. Edwards also testified that, based on the labeling, advertising and marketing of the JAX lubricants containing Micronox antimicrobial technology, it was his opinion that Behnke's lubricants were not exempt from FIFRA under 40 C.F.R. § 152.5(d):

Q. Okay. Thank you. And earlier you mentioned that you're familiar with the exemptions found in FIFRA and its regulations, correct?
A. That's right.
Q. All right. What exemption in particular deals with on or in processed food in FIFRA or its implementing regulations?
A. 40 CFR 152.5 defines what we can consider to be a pest.
0322
Q. Okay. And what does it state? And if you want to look at the regulations, I'm happy to pass them to you.
A. I mean, in general it goes through and defines a number of items as being a pest, and then it gets specific into microorganisms and talks about microorganisms, specifically bacteria, viruses and fungi are considered to be a pest, and then there's an exception.
Q. Okay.
A. And then it says, except when they occur in or on living man or animal, processed animal feed, processed food, and then drugs, cosmetics or beverages.
Q. Okay. Focusing --
A. So those are excluded.
Q. Okay. Focusing on the portion that talks about on or in processed food, what is your understanding of when this exemption applies?
A. When the product is to be applied directly to, in or on processed food, directly.
0323
Q. All right. And what is your understanding of the purpose of this exemption?
A. The purpose of the exemption is the fact that processed food is adequately regulated by another agency, FDA, and EPA does not need at that point to regulate materials that are applied to processed food.
Q. Can you give us an example of when the exemption does apply, the on or in processed food exemption?
A. When?
Q. Yes.
A. There was in the last several years, a Proctor & Gamble product called Fit that was sold.
MR. MCILNAY: I'm sorry. What was the name?

THE WITNESS: F-I-T. And it was intended to be applied to, specifically used in restaurants and all, and they would go out -- actually go out and treat the lettuce and other commodities in the salad bar. But they weren't treating the counter or the hard surface, but actually treating the salad, tomato, cucumber, whatever the ingredients were in that salad. That specifically would be for antimicrobial purposes.
0324
BY MS. O'MEARA:
Q. Okay.
A. Whether it be, you know, public health or spoilage, bacteria.

(April 1 Tr., 0321-0324).

Q. Okay. Based on the labeling, marketing and advertising claims made by Behnke that we've reviewed and you've reviewed, is it your opinion that the on or in processed food exemption under 152.5(d) applies to the lubricants?
A. It would be my opinion that that exemption does not apply to these products.
Q. Can you tell us why?
A. First, in reviewing the literature that has been provided, nowhere are there any directions for these lubricants to be applied directly to, in or on processed food. They are intended as lubricants. They're intended to lubricate machinery. If they do become a part of processed food, it is through incidental contact. And I think there was testimony from one of the earlier witnesses that if a lubricant were to drip onto meat, that that would -- where it dripped, it would be cut out and disposed of. So there are no use directions. In looking at the claims, some of the claims being made, the claims are being made that the antimicrobial substance is in there to protect the lubricant. The intent seems to be with some of the other claims that the lubricant is killing, they're making claims to kill microorganisms, but they would be on the surface that the lubricant would come in contact with, which would be typically a hard surface, be the machinery, be whatever it's being used to lubricate.
0330
Q. Okay. And is this with regard to all five products?
A. Yes, it is.

(April 1 Tr., 0329-0330).

Q. Okay. Based on your opinion, does the on or in processed food exemption apply in any way to the five products?
A. No, it does not.

(April 1 Tr., 0361).

A. That's the sanitizer. If you've got the use in a facility in or on directly to processed food, that is FDA. If you've got it used on an inanimate surface, and it comes in contact with that, that's going to be EPA and require registration. It may require an indirect food additive, but it's going to require registration.

(April 1 Tr., 0398). Mr. Edwards' opinion is consistent with the plain meaning of the regulatory language, and U.S. EPA's historical guidance interpreting the exemption outside the context of any litigation.

2. *Behnke's lubricants are not exempt under Section 2(mm) of FIFRA*

Behnke has argued that its lubricants are exempt from FIFRA under Section 2(mm), 7 U.S.C. § 136(mm). However, the evidence and legal authorities are overwhelming that the definition of "antimicrobial pesticide" in § 2(mm) of FIFRA does not limit FIFRA jurisdiction in any way. The proof presented by U.S. EPA includes extensive citations to legislative history and guidance which were discussed at length in Complainant's Motion to Strike and Compel (pp. 14-20 and 26-29). All of the legal arguments set forth in that motion are hereby incorporated by reference. The legislative history and the guidance cited by U.S. EPA supports the assertion that the definition of "antimicrobial pesticide" in Section 2(mm) of FIFRA only affects the timeframe in which FIFRA registration of antimicrobial pesticides must be completed, and in no way limits the definition of a "pesticide" for purposes of FIFRA registration. (Complainant's Motion to Strike and Compel, pages 14-20).

Mr. Edwards also testified at hearing on this issue, and stated an opinion consistent with Complainant's legal arguments:

Q. Mr. Edwards are you familiar with Section 2(mm) of FIFRA?
A. Yes, I am.
Q. All right. And can you tell the Court what 2(mm) says? And I can hand you your statute book if you would like to take a look at that.
A. If you'd like me to read it. I mean, in general 2(mm) defines what is considered to be an antimicrobial pesticide.
Q. Okay. I'll just hand it to you in case you need it, but go ahead. I'm sorry.
A. The whole purpose behind 2(mm).
MR. MCILNAY: Is there a question? I didn't hear you ask him about the purpose of it.
0336

MS. O'MEARA: Okay.
BY MS. O'MEARA:
Q. What is the purpose of 2(mm)?
A. The purpose of 2(mm) is simply to define what applications that we receive are subject to the time frames in Section 3(h) of FIFRA. There is no other purpose behind it. It defines which applications are subject to the time frames, and then it also lists several types of applications that are not subject to the time frames.
Q. Okay. Does Section 2(mm) in your opinion create any sort of an exemption under FIFRA for purposes of registration of antimicrobial pesticides?
A. No. What it does in there is it says that application for registration of wood preservatives, antifoulants and food uses, both food uses that involve a 409 tolerance or a 408 tolerance, are not considered to be antimicrobial pesticides, and therefore are not subject to the time frames listed in 3(h). They still require registration.

(April 1 Tr., 0335-0336). Thus, Behnke's argument and this entire defense should be rejected by this Court.

3. Behnke's intended use of the lubricants is critical in determining if the lubricants are pesticides

When determining if a particular lubricant is making pesticidal claims, the Respondent's intent is paramount. The FIFRA regulations clearly speak to this issue. 40 C.F.R. § 152.15 states in pertinent part:

A pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise): (1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or (2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide...

Mr. Edwards also testified that intent is critical in determining if a particular product is a pesticide requiring FIFRA registration. His testimony further illustrates that the claims made in connection with the product play a critical role in determining the intended use of product:

Q. Mr. Edwards, in reviewing Respondent's claims in the exhibits we've looked at, how do you determine if registration is needed or is not needed?
A. In looking at the claims, how do I determine?
Q. Yes.
A. Partly based on experience and partly based on our regulations.
Q. Okay. And based on their claims, can you infer intent?
A. Sure.
Q. And can you explain why intent plays a role in whether something needs to be registered as a pesticide or not?
A. Intent plays a role because you look at how, what the purpose -- you look at the claims and based on the claims and the usage of the product, you're making a determination based on that, that the product is either being sold with the intended purpose as a pesticide product or not. And based on the claims that are being made, it's -- these are pesticide claims, so the intent is that it be used as a pesticide product.
0318
Q. Okay. And you said you rely on regulations and guidance. Is there a particular regulation that discusses intent?
A. 152.15 talks about, in 40 CFR, what pesticide products need to be registered.
Q. Okay.
A. And it defines what's considered to be a pesticide, and then it goes into intent with the claims and all.
Q. All right. And what does 152.15 state? And if you need me to hand you the regulation to refresh your recollection, that's fine.
A. I can tell you what a pesticide product – you know, but the rest of it I would need to --
Q. Okay.
MS. O'MEARA: Your Honor, may I approach the witness?
JUDGE GUNNING: Yes.
0319
MS. O'MEARA: Thank you.
BY MS. O'MEARA:
Q. I'll give you the regulation, 40 CFR, parts 150 to 189. If you could find that particular section that you were referring to, please.
A. Okay.
Q. Okay. Without reading what it says into the record, if you could just give us a summary of what 40 CFR 152.15 states regarding intent?
A. All right. The title of it is Pesticide Products Required to be Registered. And I think the -- probably most important part is where it talks about a substance is considered to be intended for pesticidal purpose if the person who distributes or sells the substance claims, states or implies by labeling or otherwise that it can or should be used as a pesticide.
Q. Okay. And is there also agency guidance that discusses this?
A. There's guidance out with the Label Review Manual that's out on our web site and also a reference material that the reviewers have.
Q. Okay. I'd ask you to turn to Complainant's Exhibit 50, please. Let me move some of

these things out of your way, and I can hand them back to you if you need them. What is this exhibit, please?

A. It is the third edition of the Label Review Manual.

0320

Q. And does it discuss intent? I can actually refer you to EPA 924, EPA Bates number 924 of CX 50.

A. It talks about intent in Chapter 2.

Q. Okay. And what does it say about intent, just generally? You don't have to read the language if you don't need to.

A. It very closely mirrors what's in 151.15, which talks about, you know, products are considered to be pesticides if they're intended for preventing, destroying, repelling or mitigating any pest.

Q. And that was on Bates EPA number 924?

A. Yes, it is.

(April 1 Tr., 0317-0321).

Mr. Edwards also testified that when determining intent, U.S. EPA does not limit its review to the primary uses of the product but rather all intended uses of the product. (April 1 Tr., 0426).

a. Behnke made clear implicit and explicit pesticidal claims on its labeling, advertising and marketing materials

Mr. Edwards conducted a detailed review of the case file before testifying at hearing. This included a review of Behnke's labeling, advertising and marketing claims. It also included a review of the ingredient list that was provided to U.S. EPA pursuant to the Court's Order Granting, in Part, and Denying, in Part, Complainant's Motion to Compel Discovery, pages 10-11 (March 5, 2008).

At hearing, Mr. Edwards testified as to some of the labeling and advertising claims in detail and explained why he believed that Behnke had made both implicit and explicit public health claims that were pesticidal in nature. (April 1 Tr., 0271-0310). He then offered his opinion that, based on these implicit and explicit public health claims, all five lubricants in question were required to be registered under FIFRA:

Q. Okay. Then moving on, we really don't have much more to go. Mr. Edwards, in your opinion, based on Respondent's labeling, advertising and marketing claims, what is the intended purpose of the five lubricants we have been discussing?
A. I think it's -- based on the literature and all, that it's clear they're intended to function as lubricants, but they also make antimicrobial claims and, therefore, should be registered as pesticide products.

(April 1 Tr., 0360-0361).

With respect to the ingredient list, Mr. Edwards testified that, of the ingredients listed, five are known active ingredients, and that of these five, two are currently contained in registered pesticides products[18] (April 1 Tr., 0313-0317).

Furthermore, on cross examination, Behnke's attorney asked Mr. Edwards to look at the labeling of Listerine, a product that is solely under the jurisdiction of FDA.

BY MR. MCILNAY:
Q. I'm going to try to speed this up, Mr. Edwards. With the Court's permission, I'm going to show you what's been marked for identification purposes as Respondent's Exhibit 60. And I will state to you this is bottle of Listerine --
JUDGE GUNNING: 60 or 70?
MR. MCILNAY: 70, I'm sorry.
JUDGE GUNNING: Okay.

BY MR. MCILNAY:
Q. And I will state to you, for the record, this is a bottle of Listerine. Reviewing that label, that is not an EPA-registered pesticide, correct?
A. That's right, it's not registered.
Q. Because it's used to kill germs on human beings, which are excluded from the definition of pests.
A. That's right.
Q. So it comes under FDA jurisdiction as a drug product.
A. That's right.
0437
Q. And has drug facts on it.
A. That's right.

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[18] The contents of the lubricants (which must include the concentration of each of the listed ingredients) become relevant in the context of 40 C.F.R. § 152.15(a)(2). However, Behnke failed to provide a number of critical details in its ingredient list, including concentration levels and separate ingredient lists for each of the five lubricants. Without further information, it is also difficult to determine if there are any synergistic effects as the ingredients are mixed together.

Q. Can you imagine another use for Listerine?
MS. O'MEARA: Objection, Your Honor. It's absolutely not material to the issue of the lubricant.
BY MR. MCILNAY:
Q. It claims to kill germs, correct?
JUDGE GUNNING: Okay. Hold on. If you could respond to the objection.
MR. MCILNAY: I'll withdraw the question.
BY MR. MCILNAY:
Q. It claims to kill germs on that label, correct?
A. Yes.
Q. If I spilled some on the floor, might it kill the germs on the floor?
A. I don't know.
Q. Oh, okay. Thank you.

(April 1 Tr., 0436-0437). On redirect, Mr. Edwards testified that, although Listerine was under the sole jurisdiction of FDA, it could also become subject to FIFRA depending on the claims made on its labeling, therefore highlighting why the claims made in connection with the distribution or sale of a product are critical in determining the intended purpose of the product and whether the product is a pesticide under FIFRA requiring registration:

BY MS. O'MEARA:
Q. If the label said right there at the bottom that it kills Listeria, E.coli and Salmonella on the floor if it spills on the floor, would it have to be registered with EPA?
A. Yes.

(April 1 Tr., 440).

Mr. Edwards also testified to this issue when asked about a hypothetical Saran Wrap product. He testified that, if public health antimicrobial claims were made with respect to this product, the Saran Wrap would be subject to FIFRA registration requirements:

Q. And Mr. McIlnay asked you a question about Saran wrap, and he was trying to understand how water that has an antimicrobial additive into it and then makes Saran wrap. Do you remember that discussion?
A. Yes.
0428

Q. Okay. And one of the questions he asked you was regarding whether the Saran wrap needed to be registered. Do you remember that?
A. Yes.
Q. And if the Saran wrap -- your answer was, it didn't need to be registered, correct?
A. That's right. It does not.
Q. If the Saran wrap made antimicrobial claims on it that were public health nature or not, I don't think it would make a difference, would it require registration then?
A. Yes. The Saran wrap at that point would need to be registered.
Q. Under FIFRA?
A. Under FIFRA.

(April 1 Tr., 0427-0428). Therefore, it is obvious that the antimicrobial claims made by Behnke in connection with its lubricant products demonstrate that the products are intended for pesticidal purpose (i.e., for controlling food borne pathogens such as Listeria, E. coli and Salmonella).

b. Behnke cannot escape FIFRA registration requirements by shifting its position on the "intended use" of the lubricants

As discussed above, the "intended use" of the lubricants is critical in determining Respondent's liability in this matter. Prior to hearing, Respondent attempted to shift its argument regarding the intended use of its lubricants with Micronox antimicrobial technology in an attempt to fit its lubricants within the "on or in processed food" exemption found at 40 C.F.R. §152.5(d). As discussed at length in Complainant's Reply to Respondent's Response to the MAD (Reply to Response), which Complainant incorporates by reference, Respondent cannot escape FIFRA or the claims which it historically made with respect to the intended uses of its lubricants by trying to assert that its intent is now different. (Reply to Response, pages 6-11).

During the hearing, Behnke explored the possibility of shifting its position on intent with Mr. Edwards on cross examination. Mr. Edwards was clear in his explanations that, given the history and content of the advertising and marketing claims

Behnke has made with respect to its lubricants, Behnke cannot now escape FIFRA registration requirements by stating that the Micronox antimicrobial technology will only work when and if the lubricant containing Micronox makes contact with processed food. Such an eleventh-hour modification of Behnke's expression of intent is both devoid of evidentiary support and disingenuous. Mr. Edwards pointed out the "spurious" nature of such an assertion:

Q. Okay. Going on, it states, In applying this exclusion EPA has historically interpreted the words processed food and processed animal feed as they are commonly understood--food that has undergone processing and is intended to be consumed immediately or after some further processing or preparation. Because the commonly understood meaning of these terms applies to edible food articles, EPA has not considered food contact items such as paperboard or ceramic ware to be processed food within the meaning of that term in FIFRA and EPA's implementing regulations. Did I read that correctly?
A. That's right.
0388
Q. All right. Thus, EPA has regarded any antimicrobial substance used in or on paper, paperboard or other food contact items as a pesticide under FIFRA. Did I read that correctly?
A. That's right.
Q. All right. In your mind, is there a distinction between a food contact item and a food additive?
A. A food contact item and a food additive?
Q. Correct.
A. Yes.
Q. Okay. And is that relevant to you in making your decisions as to whether or not a product -- whether it's a food additive or a food contact item, is that relevant to making your determination whether the product need be registered as a pesticide?
0389
A. Well, if you have an antimicrobial applied to a hard surface, such as a countertop, as a sanitizer -- that is a food contact or food processing equipment, as a sanitizer, those are EPA -- that is EPA's jurisdiction, and it certainly requires registration.
Q. Okay. We have no dispute there.
A. All right.
Q. Food additives?
A. Food additives? Again, if you're talking about your application directly to or on processed food, then that is not subject to EPA. It is FDA's, and a registration is not required. If it is applied to a substance that will indirectly come in contact with processed food, then a food additive may be required, a registration would be required because you're not applying it directly to that food commodity, but to an

inanimate surface. And if that food commodity comes in contact and there is a transfer of residue, then a food additive is likely to be required.

0390

Q. Is that true regardless of the claims that are made with regard to the food additive, antimicrobial claims?

A. To the food additive.

Q. Right. You're an expert witness.

A. You're talking about claims made that's being applied directly to that. If it's not being applied to it, then I'm not sure what you're talking about in terms of claims.

Q. Let me clear it up.

A. You need to clarify it.

Q. Okay. Hypothetically, if the claim were limited to this product when it is -- becomes a food additive, resists and even mitigates microbes found in or on the food to which it becomes an additive, would that have required registration?

A. These lubricants?

Q. I'm asking generically, a product that made just that claim.

MS. O'MEARA: You're Honor, I'm having trouble understanding the question. I would ask that it be clarified.

JUDGE GUNNING: Okay.

MR. MCILNAY: Sure.

0391

THE WITNESS: Again, I --

JUDGE GUNNING: Why don't we wait for clarification.

BY MR. MCILNAY:

Q. The product I'm describing -- let's not limit it to lubricants -- states in advertising or labeling that it may reasonably be expected to become part of the food in the processing. And if it should do so, it would mitigate or control microbes in or on the processed foods. Would that require registration?

A. It depends.

Q. Okay. On what?

A. I think the first thing would be, look at what the intended use is. In the case -- let's take the lubricants as an example. If it's being used to treat the lubricant, and the lubricant is intended to lubricate equipment, would such claims still require registration? Yes. Because, again, there's an implied pesticide claim in there. If it's going to control microbes in or on processed food should it come in contact, it's going to control microbes that it may come in contact as a lubricant, lubricating machinery.

0392

Q. It doesn't state that. So where is the implication --

A. I can't ignore that.

Q. Okay.

A. All right? I would not be able to ignore the fact that there is the possibility -- and if you're making a claim as a lubricant that it's going to get in food, in the absence of directions to be applied to food, and it's intended, it seems like to me it's a rather spurious claim to begin with, to make. And it doesn't make any sense to make, because I don't understand how it's going to work. And just to put the words up there –

(April 1 Tr., 0387-0392).

As Mr. Edwards recognized, Respondent's suggestion that Behnke could avoid FIFRA regulation simply by making unsupported (and unscientific) claims that the lubricants containing the Micronox antimicrobial technology were intended only to kill microbes on processed foods, despite the fact that the lubricants are applied to equipment and not to processed food directly, is spurious. Such an argument is also contradicted by the advertising claims which Respondent has made since at least December 2001, when it began advertising the Micronox antimicrobial technology as a component of its lubricants. These advertisements all discussed the antimicrobial properties of the greases and oils which incorporated Micronox, and none mentioned any antimicrobial effect directly on processed food. (e.g., CX 8c, at EPA 0253, 0256 (2nd paragraph, suggesting Micronox will "kill the colony" of microbes in lieu of sanitization process); EPA 0270 (discussing microbial testing of grease from inside bearing cavity of equipment); EPA 0271 (discussing testing of grease "to determine the antimicrobial properties of the grease when directly inoculated" with microbes)).

c. The word "Micronox" is a pesticidal claim

Behnke testified that it sued NSF partly to get a decision on whether using the word "Micronox" would trigger FIFRA jurisdiction. It is apparent that the person best qualified to answer such a question is someone from U.S. EPA, not NSF. Mr. Edwards addressed this issue at hearing, on cross examination:

Q. Okay. Now, absent that context, and with qualification, do you have an opinion as to whether or not the trademarked name Micronox makes public health claims?
A. I would consider that trademark name to be a pesticide claim.
Q. A pesticide claim?
A. And, depending on how it's used, but if it were up there -- I mean, I would interpret

Micro to be microorganisms, and I would interpret the nox to be knockdown. So I consider that to be a pesticide claim, and it's certainly not qualified. Again, in the context of the claims made, I would consider all of that to imply public health.

Q. I agree, that it's -- within that context. So let me narrow this do-t-wn. Micronox, outside that context, inappropriately qualified, you would still interpret just that term as a pesticidal claim?

A. Yes.

0420

Q. And knockdown, what about the term knockdown leads you to the opinion that it's pesticide, a pesticide?

A. Well, if I'm knocking down microorganisms, I'm in some way inhibiting, I'm killing, I'm doing something to that organism. I'm mitigating it, you know, repelling it, doing something in context of what a pesticide is.

Q. Okay. So breaking down the lexicology here, micro means microorganism? Is that a yes?

A. That's right.

Q. And nox means knockdown in your interpretation.

A. That's right.

(April 1 Tr., 0419-0420).

On redirect, Mr. Edwards testified that he routinely works with potential registrants to answer their questions regarding claims.

Q. Okay. And he also talked to you about the word Micronox, and whether it implied claims anti -- pesticidal claims. It seems to me he was trying to ask you some questions. Would you be willing to talk to Behnke if they had questions about registration?

0429

A. Sure.

Q. Is that something you commonly do?

A. Yes, meet with companies and talk on the telephone every week, potential, perspective registrants.

Q. Okay. And when you look at the word Micronox, do you put it into context with everything that's already out there in the advertising and marketing world?

A. Yes. You have to. And for these products, yes.

(April 1 Tr., 0428-0429). Mr. Edwards' opinion is logical: the word "Micronox" clearly suggests a pesticidal effect.

4. Some of the ingredients in the lubricant are active ingredients under FIFRA

Behnke was ordered to submit the formula for each of the five lubricants to the Court and U.S. EPA prior to hearing. (March 5, 2008 Order). Although Behnke submitted a list, it clearly was not for all five lubricants, nor was it complete. (RX 68 and April 3 Tr., 0787-0792). After a careful review of the list, Mr. Edwards was able to determine that at least five of the ingredients on the list were either current active ingredients or were at sometime active ingredients in pesticides that were registered under FIFRA. Due to the insufficient information provided to U.S. EPA, he was not able to determine the concentrations of each ingredient, nor was he able to determine whether any synergistic effects would alter the combination of ingredients in some way so as to require FIFRA registration based on the ingredients alone. Absent such information, U.S. EPA is unable to determine whether 40 C.F.R. § 152.15(a)(2) applies, which too would help determine intent as set forth in this Section. (April 1 Tr., 0313-0317).

5. Behnke made pesticidal claims as part of its distribution or sales of the lubricants

Based on the documentary and testimonial evidence presented in this case, U.S. EPA has also met its burden in showing that Behnke made pesticidal claims as part of each distribution or sale of the **JAX Poly-Guard FG-2, JAX Halo-Guard FG-2, JAX Halo-Guard FG-LT, JAX Magna-Plate 78** and **JAX Magna-Plate 74** as alleged in the Complaint.

a. Count I

Respondent made pesticidal claims on the actual tube of **JAX Poly-Guard FG-2** itself, as observed by both the WDA inspector and Mr. Bonace. (CX 1, CX 38 and March 31 Tr., 0144-0145).

b. Count II

Respondent made pesticidal claims on the actual tube of **JAX Halo-Guard FG-2** itself, as observed by both the WDA inspector and Mr. Bonace. (CX 1, CX 39 and March 31 Tr., 0145-0146).

c. Count III

The evidence demonstrates that Respondent clearly made pesticidal claims with respect to **JAX Halo-Guard FG-2**. In addition to the pesticidal claims that the Respondent made on the actual tubes of **JAX Halo-Guard FG-2,** Respondent also made pesticidal claims through its advertising and marketing literature as well as through its sales person, Mr. Mike Keller. At least some of the advertising literature that was given to American by Behnke contained pesticidal claims and pre-dated the distribution or sale of the **JAX Halo-Guard FG-2** at issue in this count. Particularly, the advertising literature entitled "American Foods Group, JAX Lube-Guard Program," was dated June 20, 2003. (CX 8a, at EPA 0199; and CX 16, ¶¶ 34 through 36). This document included pesticidal claims for the entire "Halo-Guard FG" line of greases (CX 8a, at EPA 0202 ("JAX Halo-Guard FG provides Micronox microbial knockdown performance.")). The advertising literature entitled "Technology Focus, JAX Micronox™ Technology, Introducing Micronox™ Technology in JAX Food-Grade Lubricants for Microbial Knockdown Performance against Listeria, E. coli, Salmonella and other microorganisms," was dated December, 2001. (CX 8c and CX 16, ¶¶ 41 through 44). This advertising literature also made antimicrobial pesticidal claims regarding the Micronox technology. (CX 8c, at EPA 0256). Mr. Rybicki testified that the antimicrobial claims made by Behnke were one of the major reasons that American

decided to purchase the lubricants, and he further testified that American was never contacted by Behnke to redact, destroy, or replace any of the advertising literature that Behnke had previously given to American. (March 31 Tr., 0088-0089 and 0095-0096). Further, he testified that American was even willing to pay a higher price for these lubricants because they contained the Micronox antimicrobial technology. (March 31 Tr., 0089-0090). (See generally CX 16, ¶¶ 19, 21, and 46 through 50, CX 8b, at EPA 0249 and March 31 Tr., 0082-0097).

The EAB addressed the issue of when a pesticidal claim is part of the pesticide's distribution and sale in *Microban II*, in which the Board responded to Microban's argument that the claims made were not part of the distribution or sale of its products. The Board's decision states:

> *This argument is contrary to the conclusions in In re Sporicidin International, Inc., 3 E.A.D. 589 (CJO 1991). As the Chief Judicial Officer in that case explained, FIFRA is a remedial statute and, as such, "should be construed liberally so as to effectuate its purposes." Id. At 640. Therefore, "[b]roadly construing the phrase 'part of its distribution or sale' so not to require contemporaneous sale or distribution furthers the overall purposes of FIFRA." Id. Here as in Sporicidin, "[c]ommon sense suggests that a claim followed by a sale evinces nothing more that a normal cause-and-effect relationship, and that a time interval spanning the two events is common.*

Microban II, 11 E.A.D 425, at 444 (EAB 2004). Therefore, the EAB concluded that there was a sufficiently close link between the claims and the distribution or sale to prove sale or distribution of the pesticide.

Looking at the totality of the evidence in the Behnke case, it is apparent that, as was in the cases *Microban II* and *Sporicidin*, there is a sufficiently close link here to conclude that the claims made regarding **JAX Halo-Guard FG-2** did in fact induce the subsequent distribution or sale of this lubricant product to American, as set forth in Count III of the Complaint.

d. Counts IV and VI

The testimony and documentary evidence demonstrates Respondent clearly made pesticidal claims with respect to **JAX Magna-Plate 78** as well as **JAX Halo-Guard FG-2,** and that these claims were a part of the distribution of the lubricant. See discussion at c., above. (CX 8c, at EPA 0259-0260).

e. Count V

The testimony and documentary evidence demonstrate that Respondent clearly made pesticidal claims with respect to **JAX Magna-Plate 78** and that these claims were a part of the distribution of the lubricant. See discussion at c. and d., above. Additionally, it is important to note that the date of distribution or sale that took place in Count V (March 7, 2007) clearly post-dates all of the labeling and advertising literature (both print and internet) in the record.

f. Count VII

The testimony and documentary evidence demonstrates that Respondent clearly made pesticidal claims with respect to **JAX Magna-Plate 78** and that these claims were a part of the distribution of the lubricant. See discussion at c., d. and e., above.

g. Counts VIII, IX and XI

Respondent made pesticidal claims on the actual tubes of **JAX Poly-Guard FG-2** themselves, as observed by both the WDA inspector and Mr. Bonace. (See CX 1 and CX 38). Mr. Bonace also observed that the tubes of **JAX Poly-Guard FG-2** at Badger and Perlick were identical to the ones collected at the Behnke facility on August 3, 2006. – (CX 9 and 10; March 31 Tr., 0165-070).

h. Count X

Respondent made pesticidal claims on the actual tube of **JAX Halo-Guard FG-LT**, as observed by Mr. Cremers of MDA at the Jennie-O facility. (CX 15 and March 31 Tr., 0219). Additionally, even Mr. Peter of Behnke testified at hearing that Behnke generated advertising and marketing materials for its lubricants for the express purpose of inducing sales.

Q. What is the next page, for the record, EPA 0735?
A. It is a product data sheet for POLY-Guard greases.
Q. And generically, generally, what is a product data sheet?
A. It's a description of the product and its inherent characteristics for sales purposes.
Q. And you anticipated my next question. How is it used? I understand it's for sales purposes, but how is it used in your business?
A. Basically to introduce the product to a potential customer.

(April 2 Tr., 0596). See also CX 36, ¶8 at EPA-0752 and ¶17 at EPA-0755.

Given all the evidence in the record, U.S. EPA has met its burden in showing that Behnke violated FIFRA on at least eleven separate occasions as alleged in the Complaint by distributing or selling a pesticide that was unregistered on eleven different instances.

E. There is no other exemption under FIFRA that would allow Behnke to escape FIFRA requirements

In its Answer, in subsequent pleadings and at hearing, Behnke has made a number of arguments as to why its lubricants are not subject to FIFRA jurisdiction. Yet, Behnke has failed to produce any evidence or legal authority to demonstrate that any of these defenses apply. Respondent's defenses were addressed in Complainant's MAD and Complainant's Motion to Strike and Compel, and the arguments set forth in Complainant's motions are hereby incorporated by reference.

Federal courts also recognize that, as a general matter, a defense that is based on an exemption to regulatory coverage is an affirmative defense. *See United States v. First*

City Nat'l Bank of Houston, 386 U.S. 361, 366 (1967) ("where one claims the benefits of an exception to the prohibition of a statute," one generally carries the burden of proving that it falls within the exception); *In re: J. Phillip Adams*, 13 E.A.D. ___ (EAB 2007), 2007 EPA App. LEXIS 24 ("One who asserts an affirmative defense bears the burdens of producing evidence as to the defense and demonstrating, by a preponderance of the evidence, that the defense applies."); *In re Capozzi Custom Cabinets*, 11 E.A.D. 10, at 19, n. 16 (EAB 2003); *In re Rybond, Inc.*, 6 E.A.D. 614, 637 & n. 33 (EAB 1996); *In re Standard Scrap Metal Co.*, 3 E.A.D. 267, 272 (CJO 1990) ("Generally, a statutory exception (or exemption) must be raised as an affirmative defense, with the burden of persuasion and the initial burden of production upon the party that seeks to invoke the exception."). Behnke has failed to meet its burden with respect to any of the defenses or arguments it has raised.

1. *The fact that Behnke's lubricants are subject to the FFDCA has no bearing on if the lubricants are subject to FIFRA*

Behnke continues to argue that its lubricants are not subject to FIFRA because they are already subject to the FFDCA. Behnke is under the mistaken impression that its lubricants can only be subject to either the FFDCA or FIFRA, but not both. Behnke is incorrect in stating that *"the key to interpreting the ambiguity in FIFRA at the bottom of this case is whether the Lubricants are "food additives" regulated under FFDCA."* Response to MAD, at 14. The legal authorities previously cited and discussed by U.S. EPA, as well as the documentary and testimonial evidence introduced into the record, clearly demonstrate that a lubricant such as Behnke's can be subject to both the FFDCA and FIFRA.

a. *Even the FFDCA and FDA guidance clearly state that the FFDCA does not affect FIFRA jurisdiction*

The most compelling language demonstrating that the FFDCA does not in any way curtail or affect FIFRA requirements and jurisdiction can be found in the definition of "pesticide chemical" at § 201(q)(1) of the FFDCA, where it specifically states:

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.

See also Complainant's Motion to Strike and Compel, at pages 21 -26.

Further, even Respondent's own exhibit supports this assertion. RX 53, an FDA guidance document introduced by Respondent, states in pertinent part as follows:

It is important to note that, depending on the proposed use, an antimicrobial food additive may also be a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As such, it may be subject to registration as a pesticide by the EPA as well as regulation as a food additive.

(RX 53 at II, C).

Additionally, the FDA also issued guidance in July of 1999 entitled "Antimicrobial Food Additives - Guidance" (CX 20) which explains that a product can be both a "food additive" regulated under the FFDCA and a pesticide regulated under FIFRA.

By definition, a substance that is a pesticide chemical under § 201(q) is a "pesticide" within the meaning of FIFRA (§ 201(q)(1)(A) of FFDCA, as amended by ARTCA), and not a "food additive." Such pesticide chemicals are subject to pesticide registration under FIFRA. As discussed earlier, there are exceptions to the definition of a "pesticide chemical" under § 201(q)(1)(B), which exceptions are subject to regulation as food additives under § 409. However, under § 201(q)(1)(B) of FFDCA, as amended by ARTCA, such substances that are excepted from "pesticide chemical" are not excepted from the definition of a "pesticide" under FIFRA. Consequently, such substances that still meet the definition of a pesticide under FIFRA (even though, under FFDCA, they may be regulated as food additives), are subject to registration under FIFRA.

(CX 20 at EPA-0541).

See also discussion in Complainant's Motion to Strike, at pp. 27-29 and April 1 Tr., 0429-0431.

Further, Behnke remains confused about much of the discussion in the FDA's guidance document, the Food Quality Protection Act (FQPA) and the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA) relating to FDA's and U.S. EPA's regulatory authority over antimicrobial substances under the FFDCA. The documents cited by the Respondent only delineate when a product is subject to § 408 of the FFDCA (i.e. when a product falls under U.S. EPA's regulatory authority under the FFDCA) and when a product is subject to § 409 of the FFDCA (i.e. when a product falls under FDA's regulatory authority under the FFDCA). The documents concern only FFDCA regulatory jurisdiction, not FIFRA jurisdiction. None of these statutory provisions or guidance documents affects U.S. EPA's regulatory authority over antimicrobial pesticides under FIFRA.

FIFRA is a separate statute from the FFDCA, and U.S. EPA's jurisdiction under the FFDCA is separate and distinct from U.S. EPA's jurisdiction under FIFRA. As explained in Complainant's Motion to Strike and Compel, under the FFDCA, U.S. EPA is authorized to "issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food." 21 U.S.C. § 346a(b)(1). The Agency's regulatory jurisdiction under the FFDCA is limited to substances that meet the definition of "pesticide chemical" under 21 U.S.C. § 321(q)(1)(A) of the FFDCA. If a substance is a "pesticide chemical," then U.S. EPA is authorized under the FFDCA to establish or modify or revoke a tolerance for residues of that substance in or on food. If the substance is a "food additive," then FFDCA regulatory coverage of that substance is handled by the

FDA. See 21 U.S.C. § 321(q)(1)(B). In contrast, FIFRA is implemented and enforced entirely by U.S. EPA. When it comes to regulatory authority under FIFRA, U.S. EPA has complete jurisdiction over any substance that meets the definition of "pesticide" set forth in Section 2(u) of FIFRA, 7 U.S.C. § 136j(u). The FDA plays absolutely no role in the enforcement of FIFRA, and FDA regulations therefore have no effect on whether a particular substance is a "pesticide" subject to FIFRA and its implementing regulations. (Motion to Strike and Compel, at 21-26; and April 1 Tr., 0382-0409).

During the hearing in this matter, Mr. Edwards' explained the distinction between EPA's jurisdiction over a product under the FFDCA and U.S. EPA's jurisdiction over that product under FIFRA:

Q. Now, there was a lot of discussion about Complainant's Exhibit 19, and I just want to clarify that briefly. Does EPA have some involvement in the Federal Food, Drug and Cosmetics Act?
A. EPA sets tolerances or tolerance exemptions under section 408 of the Food, Drug and Cosmetic Act.
Q. Okay. And then section 409 --
A. Section 409 is there for food additives, which EPA used to use, but no longer, because we reclassified Raw Agricultural Commodities and all of the associated by-products as Raw Agricultural Commodities, so we no longer needed to set tolerances under 409.
0427
Q. Okay. So 408 is EPA?
A. And 409 is FDA.
Q. And this is all under the Federal Food --
A. Right.
Q. -- Drug and Cosmetics Act, correct?
A. That's right.
Q. And much of this discussion in Complainant's Exhibit 19 in that Federal Register is really regarding EPA's and FDA's jurisdiction in the Federal Food, Drug and Cosmetic Act; isn't that correct?
A. That's right.
Q. Did any of that discussion that occurred with
Mr. MCILNAY change your opinion as to whether these particular lubricants need to be registered under FIFRA?
A. No, not based on the claims that are on the literature.

(April 1 Tr., 0426-0427). Clearly, jurisdiction over a product under FIFRA is separate and distinct from jurisdiction under the FFDCA, and the FDA's own guidance makes it clear that the FDA does not purport to interpret U.S. EPA's FIFRA statute and regulations, and leaves it up to U.S. EPA to interpret and implement FIFRA in manner consistent with its remedial purpose.

Further, Mr. Edwards testified as to how the FIFRA registration process is affected by the FDA and FFDCA, during which testimony he confirmed that a product can be both an indirect food additive under the FFDCA and a pesticide under FIFRA:

Q. Okay. Now, you talk about indirect foods, and Respondent does claim that its lubricants are indirect food additives under FDA. In your opinion, does that have any effect on whether the lubricants have to be registered under FIFRA?
MR. MCILNAY: I'm going to object to the foundation and qualification of this client -- or this witness to interpret FDA regulations.
0333
MS. O'MEARA: May I respond?
JUDGE GUNNING: Please.
MS. O'MEARA: Thank you. I'm not actually asking Mr. Edwards to interpret the FDA regulations. What I'm asking is, when he is determining whether registration is appropriate or not, does he consider the fact that FDA has deemed the particular product an indirect food additive, does it have any impact on his decision at EPA?
MR. MCILNAY: I'll withdraw the objection with that qualification.
THE WITNESS: I think I earlier talked about the fact that we do handle applications for registration for a variety of products where FDA and indirect food additive regulation is required, but an EPA registration is also required because of where the product is intended to be used. I think I gave as an example application to water, where in the manufacture of pulp and paperboard, where you're applying it to water to control pests, bacteria, slime in the water, the residue in the water is going to end up being a component of pulp and paperboard which would come in contact with processed food. So the residue in that case is regulated by FDA, and they've actually got a citation in 21 CFR, I think it's 176.300 for slimicides. We've registered many other products for other types of uses, such as coatings. We've even registered a product intended for application as in-tube lubricants, where FDA indirect food additive was required, but an EPA registration is also required because the purpose is that it's intended to preserve the lubricant, and lubricant is not processed food.
0334
BY MS. O'MEARA:
Q. And with respect to these particular lubricants, the fact that they may or may not be indirect food additives under FIFRA, does that have any impact on your deciding whether registration is appropriate under FIFRA?

A. No. FIFRA -- I mean, what we would do is we would require an indirect food additive regulation be established or required to show us where one has been established, or we would not register the product.

(April 1 Tr., 0332-0334). Thus, Mr. Edwards' testimony demonstrates that, historically, U.S. EPA has required FIFRA registration for antimicrobial products that are also subject to the indirect food additives regulations of the FFDCA. (See Motion to Strike and Compel, pp. 26-29).

Mr. Edwards also provided a number of examples where a product that was required to be registered under FIFRA was also subject to the FFDCA (April 1 Tr., 0337-0358). Among the examples of other registered products was a lubricant that was subject to regulation under the FFDCA as a lubricant and also subject to regulation under FIFRA as an antimicrobial pesticide. Mr. Edwards also testified to the similarities between the Behnke's lubricants and this FIFRA registered product:

Q. Now, Mr. MCILNAY talked to you about MICROL a little bit. Can you tell the Court if there is any similarity between MICROL, the Petro Canada product in 18e of Complainant's exhibits, and Micronox, the products we're talking about today, the lubricants containing the Micronox?
A. Well, I mean MICROL contains benzoic acid, and it's registered to be -- it can be incorporated into food-grade lubricants. Micronox is incorporated into food-grade lubricants. MICROL makes no public health claims. It's in there to preserve the lubricant, to control odors in the lubricant. While the Micronox makes public health claims for the lubricants.
0425
Q. Okay.
A. So there are similarities, and there are differences.
Q. Now, if MICROL were to make public health claims, would the additive have to be registered or would the actual lubricant have to be registered?
A. If the lubricant made any reference to a public health claim, then the lubricant would have to be registered.
Q. Thank you.
A. MICROL could -- yeah, it could submit efficacy data, and they could demonstrate that they control public health. But, again, you take that and add it to a lubricant, the lubricant could not make a public health claim without being registered.

(April 1 Tr., 0424-0425).

Based on concrete documentary evidence, coupled with actual examples of FIFRA pesticides that are also subject to regulation as food additives under the FFDCA, it is clear that there is some overlapping jurisdiction. In this instance, Behnke's lubricants are subject to the FFDCA as lubricants, and are also subject to FIFRA as pesticides.

b. It is irrelevant if the lubricants are "food additives" under the FFDCA when determining FIFRA jurisdiction

Respondent has also argued in its pleadings that its lubricants are regulated as "food additives" under the FFDCA, and that this removes its lubricants from regulation under FIFRA. (See Answer, p. 28). However, the lone statutory citation provided by Respondent in support of this argument, 21 U.S.C. §321(s), is a section of the FFDCA, and it has no impact on the definition of the term "pesticide" under FIFRA. Respondent has provided nothing to show that its lubricants' status as a "food additives" somehow exempts them from regulation as pesticides under FIFRA. To the contrary, as revealed in the legislative history cited above in connection with Complainant's Motion to Strike and Compel, the fact that a product is a "food additive" will not operate to exempt that product from regulatory coverage under FIFRA, for Congress clearly envisioned that "food additives" could also be pesticides regulated under FIFRA. As stated by Rep. Clayton in connection with the passage of ARTCA, "[a]ntimicrobials will still be subject to registration under FIFRA and standard FDA review for food additives." (144 Cong Rec E 2197). This expression of legislative intent demonstrates that Congress understood that a product could be subject to regulation both as a pesticide under FIFRA and as a "food additive" under the FFDCA. (Motion to Strike Compel, at pages 21-29 and Section D.(2) above).

2. *FIFRA requires registration of pesticides regardless of the industry that purchases them*

Benhke also argues that its lubricants should not be subject to FIFRA registration because the lubricants were only being offered for sale to a highly sophisticated food industry[19]. However, Behnke failed to support this argument at hearing.

Furthermore, Mr. Edwards testified on this issue, explaining that there is no exemption under FIFRA for antimicrobial products that are sold primarily or even exclusively to the food and beverage industry:

Q. Mr. Edwards, does FIFRA exempt from registration microbial products, in your opinion, that target only the food and beverage industry?
A. No. I mean, it would exempt antimicrobials that are applied directly to beverages and directly to processed food. But if you're not applying it directly to, in or on that, no.

(April 1 Tr., 0337).

In fact, as Dr. Blackburn testified, subjecting antimicrobial products to the rigors of an efficacy evaluation and the other requirements of FIFRA registration is particularly important where the products are intended for use in a food processing plant. Dr. Blackburn testified that efficacy evaluations are particularly important where an antimicrobial product is to be used in a food processing situation, because the end product is something that is to be ingested, and in order to ensure that food-borne

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[19] Even the testimony presented by Behnke undermines its argument that the food industry is highly sophisticated. Mr. Cooper, one of its own witnesses, testified that one of the members of the food processing industry was using WD-40 to lubricate equipment that handles fresh chickens. (April 3 Tr., 0847-0849). If the owners and operators of a food processing plant are capable of making this type of flawed operational decision, there is a realistic danger that some owners and operators of facilities responsible for processing food could misuse lubricants which are claimed to have antimicrobial properties (e.g., by mistakenly believing that the use of such lubricants can serve as a substitute for equipment sanitization processes). (CX 8c, at EPA 0256 and April 1 Tr., 0507-0508).

pathogens are being mitigated as claimed, it is important to know that the antimicrobial products will be effective against these microorganisms.

Q Are there situations in which an efficacy evaluation is particularly important?
A I think in all situations, but more importantly in your hospital settings, and also in your food processing areas.
Q And why is an efficacy evaluation particularly important in a food processing situation?
A Well, in the food processing establishment your end product is going to be something that's going to be ingested, and it's important that proper products are used to mitigate public health organisms from getting in the food, from causing the diseases associated with food and by addressing the efficacy at the beginning of the process and knowing that the products that are to be used in these facilities are indeed efficacious, you can mitigate a lot of these infections or these pathologies.

(April 1 Tr., 0496-0497).

Further both Mr. Edwards and Mr. Peter both testified that the lubricants in question could be used for non-food uses, therefore completely undermining Behnke's argument that it lubricants are being used by a specialized industry. Mr. Edwards testified as to this issue:

BY MS. O'MEARA:
Q. Mr. Edwards, can you imagine any other uses for the antimicrobial lubricant?
A. For this particular --
Q. Yes.
A. I don't know, just looking at the advertising, that it's restricted to sale only to use in food processing --
Q. Okay.
0423
A. -- circumstances. I mean, if it were used in a nonfood, I see nothing -- I've seen nothing with the advertising or other literature that would prevent it. In fact, some companies might be willing to pay more for this type of lubricant knowing that it is intended for food, and they might use it in nonfood situations.
Q. Okay. Could you imagine that perhaps lubricant could fall on the floor in a food processing facility?

A. Sure.
Q. And would it, according to the claims that you read, kill microorganisms on that floor?
MR. MCILNAY: Objection, Your Honor. This is speculative at best. I mean, it could.
MS. O'MEARA: May I respond?
JUDGE GUNNING: Yes.
MS. O'MEARA: The claims that have been made over and over again is that the lubricants contain Micronox in it, that they're part of, incorporated in the -- I'm sorry – the lubricants, yes, contain the Micronox in it, and they're incorporated in the lubricant. So as a result, Micronox is going to go along with the lubricant wherever the lubricant will fall. So I don't think there is much speculation based on these claims to answer that question.
0424
JUDGE GUNNING: I'll allow that question.
THE WITNESS: I mean, it certainly could. We would consider the floor to be a nonfood use.
BY MS. O'MEARA:
Q. I'm sorry. Say that again.
A. We would consider the floor to be a nonfood use.
Q. Okay. And in the claims and advertising that you reviewed, were there some claims that were unqualified, and didn't specify where the microorganisms were being targeted?
A. That's right. There were some.

(April 1 Tr., 0422-0424).

Mr. Peter also testified that the lubricants could be used for non-food purposes, that he could not control how his lubricants would be used, and that he would sell them to anyone who was willing to buy them. (April 2 Tr., 0642-0645 and 0710-0711).

3. Behnke's testing of the lubricants does not exempt them from FIFRA jurisdiction

During the hearing Behnke implied that FIFRA registration was not needed for its lubricants not only because Behnke only sold its lubricants to a sophisticated market, but also because the food industry does its own testing. Behnke failed to provide any evidence on the specific standards or methodologies involved in such testing, nor did Behnke demonstrate how such testing would exempt the lubricants from FIFRA requirements. To the contrary, the evidence was overwhelming that the efficacy data

specifically required by U.S. EPA is critical when public health claims are being made, as was the case for Behnke's lubricants. Both Mr. Edwards and Dr. Blackburn testified on this issue. (April 1 Tr., 0248-0250 and April 1 – 2, Tr. 0487, 0489-0490, 0496-0497 and 0514-0516).

Additionally, Dr. Blackburn testified why it was so important to require an efficacy evaluation for the JAX lubricants containing Micronox antimicrobial technology, especially in light of the language referencing "a sanitization process," which suggests that the lubricants could serve as a substitute to a rigorous sanitization process required in a food processing plant:

Q. Thank you. Dr. Blackburn, I would like to show you another exhibit. It's Complainant's Exhibit 8c, and the page is EPA 0256. And I do have an enlarged version if that's easier for you, Dr. Blackburn. Do you recognize this exhibit?
A. Yes.
Q. And is this a document you reviewed as part of your work in this case?
A. Yes.
Q. Now, for the record, what is being discussed on this particular page?
A. The JAX Micronox Technology.
0507
Q. Now, are there any statements on this particular document that are of concern to you?
A. Yes.
Q. Which statements?
A. The reference again to the product exhibiting broad-spectrum antimicrobial activity against gram-positive and gram-negative bacteria, yeasts and molds. The statement in general that, all the antimicrobial agents utilized, the reference to knockdown performance, and lastly, the statement, if a bacteria, yeast or mold colony is already established FDA/USDA/NSF-approved competitor lubricants will inhibit the growth of the colony, but to actually kill the colony will require a sanitization process or the use of the JAX food-grade lubricants which incorporate Micronox technology.
Q. And in particular, the final statement, why is that claim of concern to you?
A. It's concerning to me because it implies or directly implicitly states that this product can be used as a substitution for the sanitization process.
Q. And if a product came in for your review, would you ever approve a label with this language?
0508
A. No.
Q. Would you require an efficacy evaluation for this Micronox technology?
A. Yes.

Q. Okay. And I take it you believe an efficacy evaluation is important for this technology?
A. Yes.
Q. And why do you consider it important?
A. Again, there are public health claims being made here, and what's really disheartening to me is the statement about the sanitization process and how a lubricant can replace that process. And that process is -- having worked in a food production facility and seeing how extensive that process is and the volumes of water and sanitizer that have to be used, substituting that process with a lubricant is alarming.

(April 1 Tr., 0506-0508).

Furthermore, there was testimony regarding the shortcomings and information deficiencies of the testing documentation furnished by Respondent in its advertising literature. Dr. Blackburn testified as to the types of data needed for efficacy testing, including the submission of a testing protocol; the appropriate levels of inoculums needed in such testing; the implementation of good laboratory practices (GLP) in the testing; identification of the contact times employed to evaluate the product's effectiveness as an antimicrobial; the use of a neutralization process following passage of the contact time; and the use of a reliable source of microorganisms when choosing the microorganisms to be used for testing purposes. (April 1 Tr., 0492-0495). She also testified as to the testing information that was provided by Behnke in its advertising and marketing literature and determined that it was inadequate to meet U.S. EPA standards for efficacy testing. (April 1 Tr., 0504-0505, 0508, 0514-0516).

Mr. Peter testified that Behnke had never submitted any efficacy testing data to any governmental agency, much less to U.S. EPA. (April 2 Tr., 0716-0717). Mr. Troy Paquette, Behnke's Technical Director, admitted on cross examination that any testing that was done either by an independent lab or by any of Behnke's customers did not meet the U.S. EPA efficacy testing standards. (April 3 Tr., 0793-0804).

F. Behnke made calculated business decisions to avoid seeking U.S. EPA's opinion regarding its lubricants

During the testimony of Mr. Peter, it became evident that Behnke was cognizant that its labeling, advertising and marketing claims for its lubricants may have triggered FIFRA jurisdiction. Rather than reach out to U.S. EPA to determine if Behnke was in compliance with FIFRA, Respondent made concerted business decisions to avoid contacting U.S. EPA to determine whether the Agency believed that the products were subject to FIFRA's registration requirements.

Dating back to 2003, Behnke was first made aware that its labeling, advertising and marketing claims associated with its lubricants may implicate FIFRA. (CX 36, at EPA 0755, and April 2 Tr., 0657-0658). However, Behnke did not take an active role in determining whether it was in compliance with U.S. EPA requirements, because it rejected the possibility of being regulated by both U.S. EPA and the FDA. In Behnke's opinion, its lubricants were only subject to FDA requirements and it did not want to be told otherwise. (April 2 Tr., 0660-0661, 0669.) Adhering to its flawed legal reasoning, Behnke never once considered contacting U.S. EPA on its own volition to seek clarification on the issue. (April 2 Tr. 0665 – 0666). Although Mr. Peter testified that Behnke did some research to determine if FIFRA applied to its lubricants, it was clear that the research performed by Respondent was half-hearted and cursory; and, more often than not, it focused on the FDA regulations, not U.S. EPA requirements. (April 2 Tr. 0660-0661). Not once did Behnke seek the advice of U.S. EPA in a genuine manner. On the contrary, it chose to put its head in the sand and proceed as it saw fit, without making a candid effort to determine if its lubricants should be registered with U.S. EPA pursuant to FIFRA. Even following a nearly four-day hearing, and after listening to U.S. EPA's

experts testify under oath about these subjecs, Behnke continues to take the obstinate position that its lubricants are only subject to FDA requirements.

Behnke's blatant disregard for the law was evident by the fact that, even up to the date of trial, U.S. EPA was able to find pesticidal claims on Respondent's website and associated links. (March 31 Tr., 0195, 0201-0202). Furthermore, on a number of instances during cross examination, Mr. Peter was unable to reconcile discrepancies between documents in the record and his own testimony[20]. The following is just a sampling of the testimony that demonstrates Behnke's refusal to make a sincere effort to understand the ramifications of FIFRA as they relate to Respondent's lubricants.

1. Behnke ignores "red flags"

On direct examination, Mr. Peter testified about Behnke's research into the regulatory status of its lubricant as follows:

Q. And do you recall approximately when Behnke was first approached with a concern about labeling relative to the H1 products?
A. I would say it was probably sometime in 2003.
Q. All right. And initially I want you to tell the Court what the concern was that was conveyed to you.
A. The concern was conveyed to me that they thought that this would be -- possibly run amuck of some EPA pesticide concerns.
Q. All right. And what, if anything, did you do in response to that contact?
0600
A. I asked them if we could meet and discuss that, because we did not feel it did, based on the type of product it was.
Q. And before we get to the meeting, at that time, approximately 2003, it was your understanding or your belief that it didn't run amuck of --
A. It wasn't my belief. But we used FDA guidelines, so the crossover to EPA was very limited when we did our study of what we could say and what we couldn't say.
Q. What study are you referring to when you say, what we could say and what we couldn't say?
A. Well, back up a little bit. When we decided we had what was a pretty neat technology here to help food processors, we discussed it, and said, is there a way to incorporate it in more products, and is there a way to promote it as a benefit to the

[20] This inconsistency calls into question the credibility of Mr. Peter's testimony.

processing plants? So we did our own efficacy studies, and continue to do some -- not in-house, but we sent those out -- and to reconfirm that we had something that was actually doing something. And then we did studies of the FDA documentation to see what we thought we could and couldn't say.

0601

Q. When you say we --
A. Troy Paquette. We as a company, Troy Paquette primarily, and I, doing some research on what we may or may not say in terms of the ability of the Micronox to help these plants control some bacteria.
Q. And I want to make it clear. You personally participated in the review of that information?
A. Yes.
Q. All right. And is it fair to assume that within Behnke you were the ultimate decision maker as to what you were going to say and not say?
A. Yes.
Q. None of this could have occurred without your prior approval?
A. I would take responsibility for it, but things happen that I'm not always aware of. But in this case, I was aware of the language.
Q. Okay. So that was the mind-set with which you left, or you requested the meeting with NSF in approximately 2003?
A. No. And 2003 may not be an accurate date. It may have been 2004, because the meeting we had was in 2005. So there might not have been red flags sent up on any of this stuff until 2004, because I don't think the lag time between when we started having issues on the labeling was that long before I requested a meeting with NSF.

(April 2 Tr., 0599-0602). Conspicuously missing from Mr. Peter's recounting of the events is any indication that Behnke ever attempted to contact U.S. EPA to clarify the regulatory status of its lubricants under FIFRA.

Later, on cross examination of Mr. Peter, Behnke's seemingly obstinate refusal to consult with U.S. EPA (the agency responsible for implementing and enforcing FIFRA) became even more apparent:

A. In 2003, NSF contacted Behnke and informed it that NSF considered that references to some antimicrobial properties of Micronox in association with products certified by NSF were improper.
Q. Thank you. That's good. So now are you clear that it was 2003, not 2004 when NSF began to --
A. Yes.
Q. -- throw up red flags for you?
A. Well, I was unclear whether it was 2003 or 2004.
Q. Okay. I just want to make sure we're clear on the date.

A. Right.
Q. And you said that you -- after they contacted you in 2003 and told you that there was a concern, they thought that your lubricants might be EPA -- need EPA registration, you said you met with them, correct?
A. Correct.
Q. Or you discussed it with them. Correct?
A. In 2003?
Q. Yes.
A. I don't recall having a discussion in 2003 with them.
0659
Q. Okay. So after NSF asked -- told you, made you aware of the fact that you might be subject to FIFRA requirements under U.S. EPA in 2003, did you meet with them?
A. I did not meet with them until 2005, and there was no mention of FIFRA from EPA at that point in time.
Q. Okay.
A. I mean, from NSF at that time.
Q. From NSF.
A. Correct.
Q. Okay. But they told you they were concerned with the labeling, right?
A. Correct.
Q. Okay. And they said it was improper, the labeling, that was their concern?
A. They had said it was improper on, it looks like, several occasions before that, too. So, yeah, that was their concern.
Q. All right. Did they tell you why they thought it was improper?
A. They thought that the claims may --
Q. Well, without looking at that, Mr. Peter. Or maybe I can restate the question. Did you ask them why they thought it was improper?
0660
A. I don't recall having that conversation.
Q. Okay. Thank you. Did you ever at that time, in 2003, try to talk to the EPA?
A. No.
Q. Okay. I'm sorry. I didn't hear you.
A. No.
Q. But your testimony was that was a red flag to you, and you said 2003 -- I mean, 2004, but we've clarified that it's 2003, that at this point this was a red flag to you. That was your testimony, correct?
A. The word red flag?
Q. Yes. You don't recall that?
A. No.
Q. You said at that time you began to do some research, though, correct to determine what the problem was?
A. We had done some research with the FDA guidelines from the beginning.
Q. When did you start to do research with EPA requirements?
A. We did not consider ourselves an EPA-regulated product, so we did not do a lot of EPA research.

Q. You didn't do a lot of EPA --
A. We were governed by FDA, and continue to be governed by FDA.

(April 2 Tr., 0658-0661). It is clear from the testimony of Mr. Peter that Respondent was not interested in genuinely researching the applicability of FIFRA requirements to Behnke's lubricants. Rather, Behnke appears to have engaged in a highly selective inquiry, looking for only those statements that could be used to support its contention that its products were only subject to the FDA.

2. *Behnke claims it did not understand what "labeling" meant under FIFRA*

Behnke also asserts that it had no understanding of the term "labeling" as used under FIFRA:

Q. Okay. Now, I want you to put yourself back in 2004. You used the term labeling. How did you understand that term then?
A. Well, customarily in the trade and with any documentation that we sent in to USDA, FSIS for approvals, when we sent a label, we sent something very similar to what you showed in EPA. It's what is applied to the container.
0738.
Q. All right. Was it in your mind that it would include the product data sheets?
A. No.
Q. So you requested a meeting with the NSF to better understand what the concern was?
A. Yes, because they had started to raise issues with what we were claiming on our labels.
Q. All right. And did such a meeting take place?
A. Yes.
Q. Approximately when?
A. Approximately May 23, 2005.
Q. All right. And where did the meeting take place?
A. I personally was in Ann Arbor, Michigan, and Troy Paquette was on the speaker phone back at our office.
0603
Q. All right. And was there somebody from NSF in attendance?
A. There were, I believe, four people in attendance.
Q. All right. And do you remember who from NSF was the person that was in authority, I guess?
A. The person who was most concerned with this situation was a Dr. Kenji Yano.
Q. All right. And to avoid objections as to hearsay, when you left the meeting, did you have a better -- or did you have an understanding of what NSF's concerns were at that point?

A. I had an understanding, but we basically left the meeting agreeing to disagree.

(April 2 Tr., 0602-0603, on direct examination of Mr. Peter). This passage demonstrates Behnke's willful avoidance of even the possibility that other regulatory requirements (i.e., FIFRA) applied to its lubricants.

On cross-examination, Behnke's failure to even attempt to communicate with U.S. EPA became painfully apparent. After Complainant's attorney had Mr. Peter read the definition of "labeling" in FIFRA and its implementing regulations, the following testimony ensued on cross examination:

Q. Okay. Thank you. Do you have a better understanding now, Mr. Peter, of what labeling means under FIFRA?
A. In regard to pesticides, I do.
Q. With regard to pesticides. Do you understand that that means the advertising material as well, such as the written material you saw yesterday?
A. With regard to pesticides.
Q. Okay. And do you understand that means marketing materials as well?
A. With regard to pesticides.
Q. And do you understand it also means any internet claims as well?
0657
A. With regard to pesticides.
Q. And any claims that might be made by your salespeople, do you understand that's what it means as well?
A. I have been made to understand that through this hearing.
Q. Now, you testified that you were contacted by NSF about the labeling on your products, correct?
A. Correct.
Q. At that time, did you try to understand what labeling meant in the context of U.S. EPA?
A. No.

(April 2 Tr., 0656-0657, on cross examination of Mr. Peter).

Behnke's actions demonstrate unmistakable negligence in ascertaining its responsibilities under applicable laws, and a refusal to acknowledge even the possibility that its products are regulated under FIFRA. As will be argued later in this brief, such

behavior warrants the imposition of a significant penalty for the violations alleged in the Complaint.

3. Behnke claims that NSF did not ask Behnke to modify claims on its advertising and marketing materials and Behnke fails to reach out to U.S. EPA for clarification

At the hearing, Respondent attempted to point out its efforts to alter its labeling to respond to the concerns raised by NSF:

Q. All right. At some point after your meeting in Ann Arbor, did Behnke take any action relative to its labeling because of the NSF issue?
A. Yes, and I think we had taken some action even before that because of some of the issues they had raised. So we were starting to pare back the claims that we made in the labeling.
0604
Q. Okay. And, again, at that point in time, when you refer to labeling, your understanding --
A. It's on the package.
Q. All right. So that didn't necessarily mean that's when you pared back on collateral literature?
A. No, no. Because -- well, in the submissions that we would make for these products, they would ask for a label, and that's what would be sent to them. So they wouldn't necessarily even have seen collateral stuff either. And that's – the label is the label.

(April 2 Tr., 0603-0604, on direct examination). Later, on cross examination of Mr. Peter, it became readily apparent that Behnke had made a conscious, deliberate decision not to contact U.S. EPA regarding FIFRA jurisdiction (a subject exclusively within the domain of U.S. EPA):

Q. Okay. In early of 2005 is it correct that NSF asked you to remove from your web site and print materials reference to Micronox having antimicrobial properties in association with any food-grade lubricants?
A. Yes.
Q. So they told you to take it out of your advertising and your print materials, as well as your labeling in 2005?
A. Yes.
Q. They did? Okay. At that time did you begin to wonder why they did that? Did you then look at any EPA regulations to figure out if labeling meant advertising and marketing?

A. We may have discussed it with Troy Paquette. But at that time, again, this is a nongovernment organization ordering us around regarding their registration process.
0665
Q. Sure. Oh, I totally understand. Did you call the EPA?
A. We did not feel our products were EPA products.
Q. So you didn't call the EPA; is that correct?
A. We did not call the EPA.
Q. You did not seek any advice from them; is that correct?
A. Nor did we receive a call from the EPA.
Q. The question was, did you call the EPA?
A. I answered the question. We did not call the EPA.
Q. And I would appreciate if you would just answer my questions. Thank you. Could you please turn to EPA 756, please, to Paragraph 21. It's just another page over.
A. Okay.
Q. Mr. Peter, could you read that paragraph out loud?
A. NSF went further and demanded that Behnke seek approval from the United States Environmental Protection Agency to register the Micronox product with the EPA as pesticide and to label and identify the Micronox product as a pesticide.
Q. Did that prompt you to call the EPA and inquire?
0666
A. No. We still felt that we were an FDA product.
Q. Did it prompt you to research the statute and regulations related to EPA just to make sure -- .
A. Yes.
Q. -- that you were just FDA?
A. Yes.
Q. You did?
A. Yes.
Q. Okay. And did you do that personally?
A. Mr. Paquette did it. I believe Mr. McIlnay assisted us to a certain extent, and I did also.
Q. But ultimately you were responsible for whatever the outcome was, correct?
A. Ultimately, I'm responsible.
Q. Okay. Do you know if Mr. Paquette called the EPA?
A. I do not know.
Q. Did you tell him to call the EPA?
A. I did not.
Q. Okay. Now, you say that in response to NSF requests you removed references to antimicrobial properties that have Micronox from the web site and the print materials; is that correct? I'm just asking. I don't think the answer is in that book.
A. No, we did not remove references to Micronox and antimicrobial from the print materials. We removed them from the labels.
0667
Q. Okay. I'm going to refer you to Paragraph 18, which is one page back. Can you read -- I'll show you -- if I may approach the witness?
JUDGE GUNNING: Yes.

BY MS. O'MEARA:

Q. -- the sentence. Starting with, In early 2005, would you please read that into the record?

A. In early 2005, NSF then demanded that Behnke remove from its web site and print materials certain references to Micronox having antimicrobial properties, even though in 2003 it had dictated to Behnke that that terminology be used. In response to this demand, Behnke removed from its web site and print materials those references to the antimicrobial properties of Micronox in association with any food-grade lubricant certified by NSF. In NSF's --

Q. Thank you. That's good. So they asked you to remove it from the advertising and the web site, but you only removed it from the labeling; is that correct?

A. Our document manager did some removing that I may not have been aware of, but there was removing of certain levels. You have to understand this went through a metamorphosis of what they were saying was allowed. And so there were levels that were removed to satisfy the requests ongoing.

0668

Q. So, but I'm just trying to understand what this document says. It says that you removed them because they requested it. Did you remove it from advertising and the web site?

A. By 2005 I think most of it had been removed.

Q. And that's antimicrobial claims and E. coli, and Salmonella and Listeria?

A. Likely references to the pathogens.

Q. Okay.

A. Again, the fact that we said Micronox or antimicrobial, we did not feel put us under FIFRA because of our FDA --

Q. So you didn't remove references to antimicrobial properties and the word Micronox, correct?

A. I don't believe we did across the board.

Q. But in this document that you reviewed and then filed a lawsuit, it says, in response to this demand, Behnke removed from its web site and print materials those references to antimicrobial properties of Micronox in association with any food-grade lubricants. Can you explain what that means then? It says you removed it. Is that incorrect, or are you stating something incorrect right now?

A. No. But properties, we may have interpreted properties to mean references to the pathogens that we were aimed at.

0669

Q. Okay. You may have. Okay. You said Behnke just didn't want to register the product with EPA, correct, the lubricants with EPA?

A. We wanted to stay out of that bailiwick.

Q. Okay. And was this because EPA controls and restricts the use of these registered products? Is that why you didn't want EPA to have jurisdiction over you?

A. We didn't want our products associated with EPA pesticides, our food-grade products.

(April 2 Tr., 0664-0669, on cross examination of Mr. Peter). This excerpt from Mr.

Peter's testimony also reveals Behnke's stubborn insistence on leaving the claims

regarding Micronox and its antimicrobial properties out in the public domain.

4. Mr. Peter meets Mr. Edwards by happenstance?

Behnke also introduced testimony about a brief meeting between Mr. Peter and Complainant's expert, Mr. Edwards. This meeting supposedly took place following a presentation given in part by Mr. Edwards; Mr. Peter spoke with Mr. Edwards and Dr. Kenji Yano (of NSF) following the presentation:

Q. Approximately how long did the three of you meet?
A. Less than an hour.
Q. What was the topic of your conversation?
A. Well, the topic of my conversation was their continuing opinion that the antimicrobial properties that would be imparted into food-grade lubricants would have to be FIFRA registered.
0610
Q. All right. And subsequent to that meeting, did you take any action to address further concerns regarding your labeling?
A. Well, we had already gone through two or three generations of labeling changes at that point in time. My further concerns revolved around the fact that we had EPA making decisions on FDA-regulated products in what I thought was a fairly arbitrary manner with no FDA involvement.
Q. Did you just ignore those concerns that were raised by --
A. No. We continued to research FDA and try and see if there was a reason for us to continue to have concern on this.

(April 2 Tr., 0609-0610, on direct examination of Mr. Peter). On cross examination of Mr. Peter regarding this meeting, it became apparent that Behnke had no interest in securing an informed opinion from U.S. EPA as to the regulatory status of Behnke's lubricant products under FIFRA:

Q. Yeah. Did you show Mr. Edwards any of your literature that day?
A. No.
Q. Any of your marketing claims?
A. No.
Q. Any of your internet web sites?
A. No.
Q. Any of your labeling?
A. No.

Q. Did you try to set up a meeting with him to do that?
A. No.
Q. Because it was a business decision, correct?
A. Correct. And because I had none of those materials with me.
Q. Okay. But you knew you were going there to talk to Dr. Yano and Mr. Edwards to find out about the treated article exemption, right?
0692
A. I did not know I was going there to talk to them. I know I was going there to listen to what they had to say.
Q. Did you go there to make sure you were in compliance with FIFRA or if you were subject to FIFRA?
A. No. I was going there to understand their interpretation of FIFRA and trying --
Q. As it applies to you?
A. -- and trying to fold it into our understanding of the FDA regulations.
Q. Okay. But you didn't bring any of the material to seek any advice from Mr. Edwards, correct?
A. No.
Q. Did you try to set up a meeting with him later on, perhaps when he got back to the office so you could provide him the materials?
A. No.
Q. Did you ask him specifically if you should register your product?
A. I did not ask. He offered his opinion.
Q. But you didn't give him all the information he needed, correct?
A. I didn't give him information, no.
MR. MCILNAY: I didn't hear. I'm sorry. Could you speak up?
0693
JUDGE GUNNING: Do you want that read back?
MR. MCILNAY: Yes, please.
JUDGE GUNNING: Just the answer?
MR. MCILNAY: The answer is fine.
(The answer was read.)
MR. MCILNAY: Thank you.
BY MS. O'MEARA:
Q. And you didn't send him any information regarding labeling, advertising or marketing, correct?
A. No.
Q. Another business decision, right?
A. Correct.
Q. Did you continue to do research after that when you got back to the office with Mr. Paquette?
A. We were doing ongoing research.
Q. With respect to EPA?
A. With respect to our labeling.
Q. With respect to EPA?
A. EPA documents were in and among the FDA documents that we had.

Q. Did you do any research to determine if you had to register your products under FIFRA with EPA?
A. We had done extensive research to determine whether we had to register our products under FIFRA with EPA. It was ongoing.
0694
Q. Now, you said, when Mr. McIlnay asked you about what you did to address the labeling concerns, that had been red flagged for you by NSF after this meeting, you said you felt that EPA was making FDA -- I don't remember exactly – but making decisions about FDA products that were arbitrary in manner, correct?
A. I may have.
Q. Okay. Was that based on your conversation with Mr. Edwards? Because you were talking about it right after you talked about the meeting, or right when you were talking about the meeting.
A. I don't believe so.
Q. So what did you believe -- how did you believe EPA was arbitrary? Based on what conversation did you determine that we were being arbitrary. Was there a conversation with EPA that led you to that conclusion that we were arbitrary?
A. It likely was the conversation that Dr. Edwards -- I mean, that Mr. Edwards had with Dr. Yano down there.
Q. So you didn't like what he had to say is what I can glean from that, correct?
0695
A. I disagreed with what he had to say.
Q. I see. And you said it was a business decision to file the litigation you did against NSF, correct?
A. Correct.
Q. And it was a business decision then to ignore EPA; is that correct?
A. EPA had not contacted us yet.
Q. But you hadn't contacted them, correct?
A. Correct.
Q. And you knew that there was some issue, correct?
A. Not from EPA, I did not.
Q. NSF -- didn't you just say that NSF told you that you might have to register your EPA lubricants, correct?
A. EPA may have had an issue with NSF, but to the best of my knowledge, EPA at that point had no issue with us.
Q. I understand that EPA didn't contact you. What I'm trying to find out is, did you have some knowledge through NSF that perhaps EPA would have jurisdiction over your lubricants?
A. We --
Q. Yes or no?
A. If you're leading me with that question, I can't answer it the way you asked it.
0696
Q. It's a yes or no question.
A. It's not a yes or no question.

(April 2 Tr., 0691-0696, on cross examination of Mr. Peter). Mr. Peter's evasiveness notwithstanding, his testimony reveals that Behnke made a "business decision" to avoid communication with U.S. EPA regarding the regulatory status of Respondent's lubricants under FIFRA.

5. Behnke continues to avoid the inevitable

Behnke's persistent refusal to acknowledge (or even sincerely inquire about) the possibility of FIFRA regulatory jurisdiction over its lubricant products continued even after the August 2006 inspection of Respondent's operation by the WDA:

Q. Okay. From the time of your brief meeting with Mr. Edwards in Florida to October of 2006, had you been contacted, or to your knowledge had anyone at Behnke been contacted by the Environmental Protection Agency relative to Micronox?
0616
A. No.

(April 2 Tr., 0615-0616, on direct examination of Mr. Peter).

Q. Now, on August 11, 2006, you met with Mr. Saatkamp, correct, when he came to the Menomonee Falls facility?
0697
A. Correct.
Q. And that was the Wisconsin Department of Agriculture inspector?
A. Correct.
Q. Did you understand that he was doing an inspection on behalf of EPA?
A. I understand he was picking up some materials on behalf of EPA.
Q. Did you ask him anything about your labeling, advertising, and marketing?
A. No.
Q. Another business decision?
A. I didn't think he had anything to offer. So, yes.
Q. Yes. Was that the answer, yes?
A. Yes.
Q. After Mr. Saatkamp came on August 11th, the question that Mr. McIlnay asked you was, did anyone contact you from the EPA after that inspection. Did anyone contact you from EPA? I think your answer was, no. I'm just trying to make sure I understood that.
A. No. The first contact was the intent to file
a --
Q. Did you contact the EPA at that point?
0698

A. Well, I contacted Mr. McIlnay, and we responded to the letter.
Q. Okay. So you waited for our letter to come, correct?
A. I didn't anticipate a letter coming, but it arrived.
Q. You were hoping it wouldn't come, correct?
A. Nobody wants the EPA to come calling.
Q. All right. It was a daunting letter, I imagine, yes, to get the EPA sending you a letter; is that correct?
A. I'm not easily daunted.
Q. Okay. But as you said, you don't want EPA coming to call on you, correct?
A. Correct.
Q. And it was at that point then you contacted EPA, correct?
A. Correct.

(April 2 Tr., 0696-0698, on cross examination of Mr. Peter). Rather than making any genuine effort to determine the regulatory status of its products or the Micronox antimicrobial technology under FIFRA, Behnke waited until compelled by U.S. EPA to address the issue:

Q. Isn't it true that even though NSF told you that you should seek registration with EPA, you still didn't contact EPA; is that correct?
A. That's correct.
Q. And, in fact, you waited until we contacted you in 2000 -- in December of 2006; isn't that correct?
A. Correct.
Q. Was that a business decision?
A. Yes.
Q. Okay. Were you just waiting for EPA to come contact you?
A. I was hoping that eventuality would not take place.
Q. But you were willing to take that risk, correct?
A. I was willing to take that risk.
Q. And that eventuality occurred on August 3, 2006, when Mr. Saatkamp showed up at your facility; is that correct?
A. No.
Q. It didn't. It wasn't until December 22, 2006?
A. Correct.
Q. Okay. So when Mr. Saatkamp came to your facility and spoke with you, as well as Mr. Paquette and Ms. Riek, I believe, and told you that they were looking at your lubricants to see if they were in compliance with EPA, did you call EPA at that time?
0674
A. No.

Q. No. So you were still making a business decision not to make that phone call; is that correct?
A. Correct.

(April 2 Tr., 0673-0674, on cross examination of Mr. Peter).

6. Behnke continues to seek an opinion from FDA on a FIFRA matter

Behnke's own witness, Mr. Peter, acknowledged that Respondent had refused to retract the advertising literature which had made the pesticidal claims:

Q. Subsequent to the meeting in Chicago, did you make any attempt to retrieve literature that had previously been distributed to customers or potential customers that made claims that have been complained about at the hearing today?
A. No.
Q. Why is that?
0632
A. Because I felt like the ball was still up in the air. We hadn't reached a decision regarding where we stand on this. We have no opinion from FDA. We have no opinion from -- we have EPA's opinion, but we have no opinion from the agency that governs our products. That's part of the 7 frustrating part of this whole process.

(April 2 Tr., 0631-0632, on direct examination of Mr. Peter). Furthermore, since the first communication from NSF alerting Respondent to the likelihood of FIFRA jurisdiction over Behnke's lubricants, Behnke persisted in contacting the wrong agency to ask about the applicability of FIFRA:

Q. Well, let's talk about -- you testified earlier about the fact that you researched some of the EPA regulations and guidance and statutes, or you researched to see if you were in compliance with EPA?
A. We did not want to be listed under FIFRA.
Q. You did not want to be listed under FIFRA?
A. We did not want to be.
Q. Okay. So did you keep that in mind when you did research?
0654
1 A. Yes, we did.

(April 2 Tr., 0653-0654, on cross examination of Mr. Peter).

There was also testimony that revealed the existence of numerous other entities who are currently offering for sale or distribution lubricants containing the Micronox

antimicrobial technology, and who are making the kinds of pesticidal claims made by

Respondent:

BY MS. O'MEARA:
Q. Mr. Peter, if we could talk about your distributors for a moment. Is FMC one of your distributors -- or they're a private label. I'm sorry.
A. Private label customer.
Q. Let's talk about private label for a second. They're a private label customer. Do you supply them with advertising?
A. No.
Q. You don't supply them with your advertising material?
A. We supply -- we supply them with our product data sheets and other information, so if that's what you meant by the question, yes, they would have access to ours.
Q. Okay. And are you aware --
JUDGE GUNNING: If everyone could keep their voices up a little.
BY MS. O'MEARA:
Q. Are you aware that on the internet they, too, are making the same sorts of claims as Behnke is?
A. Yes, I'm aware.
708
Q. And you said that they're on call, waiting to hear from you about what changes they may have to make, correct?
A. Correct.
Q. I'm just curious. Are you waiting for this decision to -- what is the -- what event will occur before you tell them to make a change?
A. A decision on whether the EPA has jurisdiction over our products.
Q. Are you waiting -- you said earlier that you're waiting for a decision. But you couldn't come to EPA about it, correct?
A. We are an FDA-regulated item, have been for 47 years.
Q. Okay. So you --
A. So the FDA is my controlling agency. It's the agency that I go to for information.
Q. I understand. Are you waiting for FDA to tell you when or if you have to register your products with EPA?
A. I would love to hear something from FDA.
Q. And you realize, though, they don't have any jurisdiction over understanding -- as we do, over the EPA regulations and statute, correct? And they don't have the authority to make that decision, correct?
0709
A. I disagree. But --
Q. You also said that you have a number of distributors, correct?
A. Correct.
Q. And they're also on call waiting to hear from you, correct?
A. Our branded distributors that sell JAX brand? Those that know or know that we have this action pending are on call, right.
Q. Have you told everybody, all your -- how many distributors do you have, Mr. Peter?

A. I don't know the number.
Q. Over 10?
A. Yes.
Q. Over 20?
A. Over 50.
Q. Over 50. And have you contacted all your distributors about this?
A. No.

(April 2 Tr., 0707-0709, on cross examination of Mr. Peter). Therefore, not only does Behnke continue to make public health pesticidal claims, but Respondent also continues to allow its private label customers and distributors (of which there are well over fifty) to make such violative claims as well. Doing so continues to pose a danger that there will be additional sales of lubricants carrying unsubstantiated claims of effectiveness against deadly microorganisms such as Lysteria, E. coli and Salmonella, which claims further suggest that the lubricants can be substituted for proper sanitization practices.

7. Behnke makes widespread claims in an effort to increase its sales

It became clear during the hearing that Respondent used the antimicrobial claims made in its advertising literature and other labeling to increase sales of Behnke's lubricant products. Mr. Peter admitted that this was the case during his testimony:

Q. And you're aware that the general public understands that E. coli, Salmonella, and Listeria are food pathogens, correct?
A. There's been enough publicity.
Q. Yeah. And you put these types of claims in there to distinguish your lubricants from your competitor's, correct?
A. Correct.
Q. And you thought that that would actually help with your sales, correct?
A. Correct.

(April 2 Tr., 0701). The picture that emerges from the record is clear: Behnke made numerous claims that the Micronox technology incorporated into its lubricants would control disease-causing bacteria, and Respondent made these claims in an effort to generate more sales and enjoy larger profits. At the same time, Behnke adopted a

distorted view of the law (and intentionally kept itself ignorant of FIFRA) in order to avoid applicable regulatory requirements. This behavior warrants a substantial penalty.

VII. Penalty

Section 14(a) of FIFRA, 7 U.S.C. 136m, governs the assessment of civil penalties for violations of, *inter alia*, Section 12(a) of FIFRA, 7 U.S.C. 136j(a) (distribution or sale of unregistered pesticides). Section 14(a)(1) of FIFRA authorizes the assessment of civil administrative penalties of up to $ 5,000 per offense. 7 U.S.C. § 1361(a)(1). The Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, and its implementing regulations at 40 C.F.R. Part 19, increased the statutory maximum penalty to $6,500 for each violation of FIFRA that occurs on or after March 15, 2004.

Section 14(a)(4) of FIFRA sets forth the different factors which must be considered in determining the amount of the penalty to be assessed for such violations. Section 14(a)(4) of FIFRA, states in pertinent part as follows:

> In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation.

7 U.S.C. § 1361(a)(4). In an effort to implement these statutory penalty factors, U.S. EPA developed the Enforcement Response Policy for FIFRA (July 2, 1990) ("FIFRA ERP"), which sets forth a methodology for the calculation of an appropriate civil penalty in accordance with Section 14(a) of FIFRA. (CX 33). This penalty policy is "designed to provide fair and equitable treatment of the regulated community by ensuring that similar enforcement responses and comparable penalty assessments will be made for comparable violations," and is also intended "to provide for swift resolution of environmental problems and to deter future violations of FIFRA by the respondent as

well as other members of the regulated community." (CX 33, at EPA 0656). *See also In the Matter of Tremont Supply Inc.*, Docket No. FIFRA-09-99-0011, 2000 EPA ALJ LEXIS 46, at [12] (June 30, 2000). In response to the promulgation of the 2004 Civil Monetary Penalty Inflation Adjustment Rule, U.S. EPA issued a memorandum dated June 5, 2006, and entitled "Penalty Policy Supplements Pursuant to the 2004 Civil Monetary Penalty Inflation Adjustment Rule." (CX 34). This memorandum adjusted the penalty amounts set forth in the FIFRA ERP to account for inflation with respect to all violations of FIFRA occurring on or after March 15, 2004. (CX 34, at EPA 0706, 0711).

In the Complaint filed against Behnke, U.S. EPA proposed a civil penalty of $50,050 for the violations of FIFRA cited in Counts 1 through 11 of the Complaint. U.S. EPA's penalty calculation is set forth in CX 14a and CX 14b. As explained in those documents, U.S. EPA calculated the proposed penalty based on the facts and circumstances of this case, after applying the statutory penalty factors in Section 14(a)(4) of FIFRA, 7 U.S.C. §136l(a)(4), and the requirements of the FIFRA ERP.

A. Application of the Statutory Penalty Factors

U.S. EPA has met its burden to consider each of the statutory penalty factors set forth in Section 14(a)(4) of FIFRA, and has met its burdens of production and persuasion with respect to the appropriateness of the penalty proposed in the Complaint, after consideration of the statutory penalty factors set forth in Section 14(a)(4) of FIFRA, 7 U.S.C. §136l(a)(4). U.S. EPA's application of each of these statutory penalty factors to the evidence presented in this case is discussed below.

1. The Appropriateness of the Penalty to the Size of the Business of the Person Charged

U.S. EPA considered the appropriateness of the penalty to Respondent's size of business by examining publicly-available information in the form of a Dun & Bradstreet report for Behnke. (CX 14b, at EPA 0342, EPA 0348 and March 31 Tr., 0189). This Dun & Bradstreet report indicates that Behnke had gross sales in the amount of $7,900,000. Respondent has not challenged this aspect of U.S. EPA's penalty calculation.

2. The Effect on the Person's Ability to Continue in Business

Even before filing its prehearing exchange, U.S. EPA met its burden to consider the effect of the proposed penalty on Behnke's ability to continue in business. Complainant hired an outside consultant on financial analysis, Mr. Mark Ewen of Industrial Economics, and examined several different items of publicly-available information regarding Behnke's financial condition. (CX 32 (esp. EPA 0651-52)). *See also Notice of Complainant's Request for Voluntary Production of Financial Information* (June 2007). However, in its prehearing exchange, Respondent expressly waived any objection to the penalty based on the statutory factor of the effect of the penalty on Respondent's ability to continue in business. See Order Denying Complainant's Motion to Strike Respondent's Affirmative Defenses; Order Granting, in Part, and Denying, in Part, Complainant's Motion to Compel Discovery, pp. 7 and 11. As held by the EAB in *In re: New Waterbury*, 5 E.A.D. 529 (EAB 1994), to fulfill the obligation to "take into account" the statutory penalty factor of "ability to pay" in a specific case, "a respondent's ability to pay may be *presumed*[,]" and that presumption can continue until the respondent's "ability to pay" the proposed penalty "is put at issue by a respondent." *New Waterbury*, 5 E.A.D., at 541 (emphasis in original). Not only do the Consolidated Rules

require a respondent to include in its answer the "basis for opposing any proposed relief" (such as a claim that it has an "inability to pay" the proposed penalty), but the EAB has instructed that, where the respondent does raise a claim of inability to pay, the complainant "must be given access to the respondent's financial records before the start of [any] hearing." *New Waterbury*, 5 E.A.D. at 542. If the respondent does not "raise its ability to pay as an issue in its answer," or if, after having raised the claim, it "fails to produce any evidence to support an inability to pay claim after being apprized of that obligation during the pre-hearing process," it may be concluded that "any objection to the penalty based upon ability to pay has been waived under the Agency's procedural rules." *New Waterbury*, 5 E.A.D. at 542. Therefore, as Respondent has expressly waived this issue, and has produced no evidence concerning its financial condition, the issue of the effect of the penalty on Respondent's ability to continue in business has been waived.

3. The Gravity of the Violation

Complainant also has met its burdens of production and persuasion with respect to the appropriateness of the proposed penalty based on the statutory penalty factor of "the gravity of the violation." Respondent's violations involved the distribution or sale of unregistered pesticides. These pesticides were antimicrobial products which Behnke claimed would be effective against bacteria such as Listeria, E. coli and Salmonella. As explained in greater detail below, by offering such products with these antimicrobial claims for sale or distribution without having applied for FIFRA registration (and without having submitted the products to the rigorous scrutiny of U.S. EPA's efficacy evaluation process), Respondent introduced into commerce antimicrobial products which have never been proven to be effective under U.S. EPA standards in controlling microorganisms to

the degree that Behnke has claimed in its advertisements and other labeling. Therefore, Respondent's violations of FIFRA present a potential danger to public health, and involve substantial gravity.

In addition, as revealed through the testimony of its own witness, company president Eric Peter, Behnke's FIFRA violations were committed in an almost willful manner. Despite being informed by NSF as early as 2003 that, due to the antimicrobial claims made by Behnke, the lubricants which incorporated the Micronox antimicrobial technology were likely subject to U.S. EPA regulation under FIFRA, Respondent continued to sell or offer for sale these lubricants, without ever attempting to retract the antimicrobial claims. In addition, Behnke obstinately refused to even contact U.S. EPA and discuss whether or not the antimicrobial claims rendered its lubricants as pesticides within the meaning of FIFRA. See discussion at pp. 90-107, *supra*.

4. Potential Harm to the Public

Complainant's expert, Dr. Tajah Blackburn, testified about the critical importance of efficacy evaluations in order to ensure that antimicrobial products are indeed as effective as advertised in the claims made for such products. Efficacy evaluations involve a critical review of the data generated to determine the efficacy or the performance of the product as an antimicrobial. (April 1 Tr., 0459-0460). Dr. Blackburn testified that efficacy valuations are critical when reviewing an antimicrobial product, because the targeted organisms are often public health organisms, and it is important that products which are claimed to work against these pathogenic organisms are in fact effective. (April 1 Tr., 0496).

As described above, the antimicrobial claims at issue in this case targeted bacteria such as Listeria, E. coli and Salmonella. Dr. Blackburn testified that claims which mention such bacteria are "public health claims," or claims which "reference[] those pathogens that are considered to be directly infectious to man," and are of particular concern to U.S. EPA. (April 1 Tr. 0485-0487).

U.S. EPA's other expert, Mr. Dennis Edwards, expressed similar concerns over the antimicrobial claims on Behnke's lubricants. He explained that proof of an antimicrobial product's efficacy is especially important when the claims made for such an antimicrobial are public health claims, because of the dangers to human health that could arise if the claims turned out to be inaccurate. (April 1 Tr., 0250). See also April 1 Tr. 0277-0279 ("a lubricant is going to provide very little control in terms of the public health control that you need in a food processing plant. So I would look at it as possibly being either false and/or misleading to the purchaser in terms of what the product does.").

Dr. Blackburn testified about the importance of efficacy evaluations in safeguarding the public, emphasizing that efficacy evaluations will be particularly critical where an antimicrobial product is to be used in a food-processing situation, because of the need to ensure that the antimicrobial is effective in preventing microbial contamination of the end product (the food). (April 1 Tr., 0496-0497).

Dr. Blackburn's testimony also revealed the dangers that could arise if an antimicrobial product claiming to be effective against Listeria, E. coli and Salmonella ultimately failed to provide the claimed efficacy against such human pathogens, and food destined for human consumption became contaminated with the deadly bacteria. Dr. Blackburn testified about the nature of these bacteria, and described the serious illnesses

associated with each, including gastroenteritis (April 1 Tr.,0470), meningitis (April 1 Tr., 0472, 0474) and spontaneous abortions (April 1 Tr., 0474). (See generally, April 1 Tr., 0469-0475)). Her testimony revealed that these bacteria are particularly deadly to human health, thereby underscoring the importance of requiring Respondent to demonstrate the efficacy of its Micronox antimicrobial technology after Behnke disseminated claims that its lubricants would effectively mitigate or control such bacteria. By refusing to submit its lubricants or the Micronox antimicrobial technology additive to the FIFRA registration process, Respondent completely avoided the regulatory oversight necessary to evaluate the truth of such antimicrobial claims, thereby potentially exposing the public to risk of disease.

Dr. Blackburn also testified about her concerns over the specific claims that Respondent made in connection with its antimicrobial lubricant products. (See April 1 Tr. 0497-0499, 0514-0516 (**JAX POLY-Guard** greases); 0499-0505 (**Magna-Plate 78**); 0505-0506 (**Magna-Plate 74**); 0506-0508 (JAX Micronox Technology); CX 1, at EPA 0021, EPA 0023; CX 8, at EPA 0186-88; CX 8a, at EPA 0208, EPA 0211; CX 8c, at EPA 0256, EPA 0270-72)). For example, with respect to the claims made in connection with the product Magna-Plate 74 (CX 8, at EPA 0188), Dr. Blackburn first identified the language which concerned her ("... enhanced antimicrobial protection against a wide variety of microbial agents, including yeasts, molds, and gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX MICRONOX provides significant knockdown performance and has proven especially effective Listeria, E. coli and Salmonella on contact and over extended lubrication intervals"). She then proceeded to explain why she was concerned over this language.

Q Dr. Blackburn, what concerns do you have with this particular language?

A I'm concerned primarily with the use of the organisms. There's reference to a wide variety of yeasts, molds, gram-positive and gram-negative bacteria, for which efficacy data was not submitted to the agency, and these claims have not been substantiated adequately. The second paragraph that actually lists the organisms, Listeria, E. coli, and Salmonella. And, furthermore, I'm concerned about "on contact" because that implies or it explicitly states that as soon as the product makes contact with the surface that the level of efficacy can be demonstrated.

(April 1 Tr., 0502-0503). Dr. Blackburn further explained that if an antimicrobial product which came to EPA for FIFRA registration bore a label containing the language identified above, such a label would never have been approved due to its failure to provide "the ATCC designation numbers to determine which organisms were actually tested,"; the "broad mention of gram-positive and gram-negative bacteria, yeasts and molds," without an identification of "which organisms were actually tested in order to support those claims"; and the claim that the antimicrobial properties would be effective "on contact," "because none of the products that are tested and registered with the agency impart efficacy immediately.... There is usually a period of time associated with the product or exposure time associated before that product can impart efficacy." (April 1 Tr., 0503-0504).

Dr. Blackburn also testified regarding a letter signed by Mr. Troy Paquette, which was included in an advertising brochure generated by respondent (CX 8c, at EPA 0256), and which discussed the JAX Micronox Technology. (April 1 Tr., 0506). She pointed out the claims made on this letter (which had been included in Behnke's advertising

literature), and explained why she was concerned about the language used in this document:

Q Now, are there any statements on this particular document that are of concern to you?
A Yes.
Q Which statements?
A The reference again to the product exhibiting broad-spectrum antimicrobial activity against gram-positive and gram-negative bacteria, yeasts and molds. The statement in general that, all the antimicrobial agents utilized, the reference to knockdown performance, and lastly, the statement, if a bacteria, yeast or mold colony is already established FDA/USDA/NSF-approved competitor lubricants will inhibit the growth of the colony, but to actually kill the colony will require a sanitization process or the use of the JAX food-grade lubricants which incorporate Micronox technology.
Q And in particular, the final statement, why is that claim of concern to you?
A It's concerning to me because it implies or directly implicitly states that this product can be used as a substitution for the sanitization process.
Q And if a product came in for your review, would you ever approve a label with this language?
A No.

(April 1 Tr., 0507-0508). Dr. Blackburn further testified about why it was important to require an efficacy evaluation for the JAX Micronox technology, especially in light of the language in Mr. Paquette's letter referencing "a sanitization process." She explained her concerns with that particular language, pointing out that the closing sentence of the letter suggested that lubricant products containing the JAX Micronox technology could serve as a substitute for the rigorous sanitization process required in a food-processing plant:

Q Would you require an efficacy evaluation for this Micronox technology?
A Yes.

Q Okay. And I take it you believe an efficacy evaluation is important for this technology?
A Yes.
Q And why do you consider it important?
A Again, there are public health claims being made here, and what's really disheartening to me is the statement about the sanitization process and how a lubricant can replace that process. And that process is -- having worked in a food production facility and seeing how extensive that process is and the volumes of water and sanitizer that have to be used, substituting that process with a lubricant is alarming.

(April 1 Tr., 0508).

Dr. Blackburn's concerns are particularly warranted in light of what Respondent's own witness, Larry Cooper, recounted about his experience with a poultry processing facility which used WD-40 to lubricate equipment on which poultry meat was processed (April 3 Tr., 0847-0849). As noted earlier, if the owners and operators of a food processing plant are capable of making this type of operational decision, there is a realistic danger that some food processors could misuse lubricants which are claimed to have antimicrobial properties (e.g., by mistakenly believing that the use of such lubricants can serve as a substitute for equipment sanitization processes).

Dr. Blackburn also discussed her concerns with the labels and advertising and marketing literature disseminated by Respondent which made claims that Behnke's Micronox technology was effective against both gram-positive and gram-negative bacteria, and effective against yeasts and molds. She explained that the references to "gram-postive" and "gram-negative" bacteria only "tell[] the consumer briefly what organisms are going to be placed on the label," but fail to provide sufficient information to identify "which exact organism is classified as gram-positive or gram-negative."

(April 2 Tr., 0516-0517). Therefore, Dr. Blackburn stated that it was important that product efficacy be tested against the actual microorganisms that were identified in the claims "so that the end user knows and that the agency is confident after reviewing the efficacy evaluation, the data, that the product is in the efficacious and will provide the level of performance that's expected." (April 2 Tr., 0517). Dr. Blackburn further testified that, where a product makes claims of effectiveness against "yeasts and molds," an efficacy evaluation is necessary because certain yeasts and molds are considered pathogenic, and it is therefore "important to disclose which organisms were tested on the label as a point of reference[,] and to insure [sic]that ... the product will perform at the level which it is intended to perform." (April 2 Tr., 0517).

Dr. Blackburn also pointed out the important information that was missing from the technical data which Respondent had generated. For example, she examined technical literature which purported to compare the antimicrobial properties of Behnke's Magna-Plate 70 Fluids with those of a competitor's lubricant (CX 8, at EPA 0186-87), and found the data provided inadequate to demonstrate the product's efficacy as an antimicrobial. (April 1 Tr., 0500-0501). Dr. Blackburn also explained the necessity of the missing data in order to ensure that an antimicrobial's efficacy is demonstrated through sound science, which is important to protect the public. (April 1 Tr., 0501-0502). Dr. Blackburn also testified that the technical information provided in certain advertising literature failed to identify any test method which had been used to evaluate the efficacy of the Micronox antimicrobial technology. (April 1 Tr., 0504-0505 and CX 8a, at EPA 0211). She further pointed out how the draft FDA guidance document (RX 53) which Respondent sought to as evidence of FDA oversight failed to identify any reliable

scientific method by which the efficacy of an antimicrobial product could be tested; omitted any performance standards that would apply to antimicrobials; failed to identify the organisms which would be used to test efficacy; and generally lacked the level of detailed information required under U.S. EPA's efficacy evaluation guidelines. (April 2 Tr., 0537-0539, 0543-0544). (*Compare* April 1 Tr., 0459-0460, 0462-0463, 0467-0469, 0481-0485; 0489-0490, 0492-0495; CX 51, CX 54, CX 55, CX 56).

Dr. Blackburn's testimony underscores the importance of requiring FIFRA registration of products which make the types of claims that Behnke made for the lubricants incorporating the Micronox technology. Such antimicrobial claims must be evaluated under reliable scientific principles and methods in order to ensure that they are as effective in controlling human pathogens and other microbes as their advertisements claim.

Dr. Blackburn's testimony demonstrates the severe gravity of the violations alleged in the Complaint. Respondent's violations created a potential danger to public health through Behnke's failure to submit these antimicrobial products, or the underlying Micronox antimicrobial technology, to the FIFRA registration process and the scrutiny of the Efficacy Evaluation in particular. The gravity of the violations as based on potential danger to the public alone warrants an appropriate penalty.

In addition, Respondent has demonstrated a high degree of culpability, and a complete failure to exercise any care to correct the violations. As noted *supra* (see pages 90-107), Respondent refused to contact U.S. EPA to ascertain whether FIFRA applied to its lubricant products in light of the numerous antimicrobial claims which it made, despite being alerted to this issue as early as 2003. See discussion at pages 90-107, *supra*.

Moreover, even after the filing of the Complaint in this matter, and up to the first day of the hearing (March 31, 2008), Respondent failed to remove many of the antimicrobial pesticidal claims at issue from its website, jax.com. As noted above, U.S. EPA inspector Terence Bonace testified that, on the first day of the hearing, he had visited Respondent's website and found that Behnke continued to make public health antimicrobial pesticidal claims on its website and associated web links. (March 31 Tr., 0201-0202 and April 2 Tr., 0629-0632, 0706). And Respondent's president, Eric Peter, testified that Behnke continues to use the words "Micronox" and "antimicrobial" on the labels of more than 80 of its lubricants containing the Micronox antimicrobial technology. (April 2 Tr., 0652-0653). He also testified that, despite the Complaint filed against Behnke, Respondent has made no effort to retrieve the literature sent to Behnke's customers which makes the pesticidal claims at issue, and that Respondent has not instructed its "private label" customers to remove the offending claims.

Q Subsequent to the meeting in Chicago, did you make any attempt to retrieve literature that had previously been distributed to customers or potential customers that made claims that have been complained about at the hearing today?
A No.
Q Why is that?
0632
A Because I felt like the ball was still up in the air. We hadn't reached a decision regarding where we stand on this. We have no opinion from FDA. We have no opinion from -- we have EPA's opinion, but we have no opinion from the agency that governs our products. That's part of the frustrating part of this whole process.
Q All right. You also market some products that are private -- I mean, you manufacture products that are private labeled?
A Yes.
Q And one of those private labels is FMC. Do I

have the name right?
A Correct.
Q And, for the record, can you describe what that means when something is private labeled?
A Companies will have us relabel our products under their name and their brand name so they may sell them through their parts distribution or use them on their equipment as the OEM build it, and then recommend that those products of theirs be used subsequently on their equipment in the field.
Q Okay. You used the term OAM.
A OEM.
Q OEM, what does that mean?
0633
A That means original equipment manufacturer.
Q Okay. So the concept is that to their consumers, this appears to be their product, they've put their label on it?
A Correct.
Q How much, if any, input does Behnke have into the content of its private label customers, what they put into their labels?
A We generally don't have any input, per se, but we'll supply them with the labeling that we use.
Q All right. Do you actually put the labels on their products in your plant?
A Yes. It goes out the door as their product.
Q All right. What steps, if any, did you take subsequent to our meeting with EPA in February of 2007, to address claims that might be made on a private labeled product?
A With FMC, I didn't take any steps with their labels because I don't necessarily control their labels, but I told them about the concerns that EPA had raised regarding Micronox and that they may want to make -- I didn't even ask them to make it. I said, be on call to hear if some changes have to be made regarding those labels.
Q Did you advise FMC that you had received an EPA
0634
notice of intent to file an action?
A It has come up, and they are aware of it.
Q Do you have other private label customers besides FMC?
A Yes.

Q Are any of them private label customers for the H1 products?
A Some are. I would say FMC is the largest.
Q Have you notified other private label customers of the fact that you received a notice of intent to file a complaint regarding labeling issues?
A Likely not.
Q Have you kept it a secret?
A No.
Q Have you made a conscious effort to contact any of those people to discuss labeling?
A No.
Q You also have a distribution network of distributors. Are these parties employees of JAX, employed by JAX?
A No. Our distributors are not employed by JAX, no.
Q All right. Are they independent business people?
A Yes.
Q All right. What communications have you had with
0635
distributors concerning their continued use of any literature that might be out there that had claims that you were made aware of that --
A Communication would have been similar to what I may have told FMC, that there are some perceived problems with the labeling, and that they should stand by for a resolution.

(April 2 Tr., 0632-0635). Later, as described above (see brief, supra, pp. 105-106) Behnke's total failure to attempt to comply with the law became apparent. (April 2 Tr., 0707-0709). Respondent's culpability is undeniably significant.

B. The FIFRA ERP's Application of FIFRA Statutory Penalty Criteria

Complainant calculated the penalty proposed in the Complaint through use of the FIFRA ERP. The FIFRA ERP establishes procedures for Agency application of the statutory penalty determination factors under Section 14(a)(4) to a particular case. Under the ERP, computation of the penalty amount is determined in a five stage process in consideration of the Section 14(a)(4) criteria. These steps are:

(1) Determination of the gravity or "level" of violation using Appendix A of the ERP;

(2) Determination of the size of the business category for the violator, found in Table 2 of the ERP;

(3) Use of the FIFRA civil penalty matrix found in Table 1 of the ERP to determine the dollar amount associated with the gravity level of the violation and the size of the business category of the violator;

(4) Further Gravity Adjustments of the base penalty in consideration of the specific characteristics of the pesticide involved, the actual or potential harm to human health and/or the environment, the compliance history of the violator, and the culpability of the violator, using the "Gravity Adjustment Criteria" found in Appendix B of the ERP; and

(5) Consideration of the effect that payment of the total civil penalty will have on the violator's ability to continue in business, in accordance with the criteria established in the ERP.

The FIFRA ERP appropriately applies the FIFRA statutory penalty criteria of Section 14(a)(4) of FIFRA, 7 U.S.C. Section 136l(a)(4). The first statutory criteria, the appropriateness of the penalty to the size of the business of the person charged, is addressed by Step 2 (the size of the business category) and Step 3 (civil penalty matrix) in the FIFRA ERP. The second statutory criteria, the effect on the person's ability to continue in business, is addressed in Step 5 (the ability to continue in business/ability to pay category) of the FIFRA ERP. Lastly, the third statutory criteria, the gravity of the violation, is also addressed in Steps 1 (gravity level category), 3 (civil penalty matrix), and 4 (gravity adjustment category) of the FIFRA ERP.

The total determination of the gravity of the violation under the FIFRA ERP is essentially a two part process: first; the appropriate gravity "level" that EPA has assigned to the violation is determined, and second; the base penalty figure is adjusted, as determined from the gravity "level," to consider the actual set of circumstances that are involved in the violation.

1. Application of the FIFRA ERP to this Case

Because gravity, size of business, and ability to continue in business factors are the same for each violation in this case, each violation has been assigned the same penalty level to calculate the proposed penalty.

a. Base Gravity Level of the Violations.

The gravity "level" established for each violation of FIFRA is listed in Appendix A of the FIFRA ERP. The "level" assigned to these violations represents an assessment of the relative gravity of each violation, which in turn is based on an average set of circumstances which considers the actual or potential harm to human health and/or the environment resulting from the violation.

Under Appendix A, the FIFRA ERP classifies a violation of 12(a)(1)(A) (distribution or sale of an unregistered pesticide) as a "Level 2" violation. Here, Complainant has assigned a Level 2 violation to each illegal distribution alleged in the Complaint.

b. Size of the Business of the Violator.

Under the FIFRA ERP, the respondent's size of business is determined by considering the respondent's gross revenue from all revenue sources during the prior calendar year. Complainant obtained a Dun & Bradstreet Report pertaining to Behnke Lubricants, Inc., printed on June 9, 2006; this report indicated that Behnke Lubricants, Inc., had a sales volume of over $7,900,000. CX 14b, Attachment A, at EPA 0348. A respondent who is alleged to have violated Section 14(a)(1) of FIFRA and whose gross revenues/sales exceed $1 million will be placed into "Business Category I." As a "14(a)(1) violator," with sales exceeding $1,000,000, Behnke was identified by

Complainant as belonging to "Business Category I." (CX 33, at EPA 0676, Table 2). As stated above, Respondent has not contested this aspect of Complainant's penalty calculation.

c. Civil Penalty Matrix

The FIFRA ERP's assignment of a base penalty relative to the gravity of the violation and size of the business occurs through a Civil Penalty Matrix. Each cell of the matrix represents the Agency's assessment of a penalty, within the statutory maximum considering each level of gravity of the violation and each size of the business category. Under the FIFRA ERP, the base penalty assigned to a violation which falls under Level 2 and Business Category I cell of the matrix is the original statutory maximum, $5,000. Based upon the requirement that EPA adjust statutory penalties for inflation pursuant to the Debt Collection Improvement Act of 1996, 40 C.F.R. part 19 and the EPA memorandum "Penalty Policy Supplements Pursuant to the 2004 Civil Monetary Penalty Inflation Adjustment Rule," Complainant used an adjusted base penalty of $6,500, reflecting the current statutory maximum penalty for each violation of FIFRA.

d. Gravity Adjustment Criteria

As the actual circumstances of the violation in this case differ from the "average" circumstances assumed in each base gravity level in the Civil Penalty Matrix, Complainant applied the Gravity Adjustment Criteria in the FIFRA ERP to the base penalty of $6,500 for each violation to correspond with the particular circumstances of this case, in accordance with the ERP. The Agency has assigned adjustments, based on the gravity adjustment criteria listed in Appendix B of the ERP, for each violation relative to the specific characteristics of the pesticide involved, the harm to human health

and/or harm to the environment, compliance history of the violator, and the culpability of the violator. The gravity adjustment values from each gravity category listed in Appendix B are then totaled. The base penalty is then raised or lowered, based on the total gravity values in Table 3 of the FIFRA ERP. Complainant calculated a Total Gravity Adjustment Value of each violation given the circumstances addressed in Appendix B of the FIFRA ERP. Appendix B is split into two components: "Gravity of Harm," and "Gravity of Misconduct." "Gravity of Harm" is further sub-divided under the FIFRA ERP under the components "Pesticide" toxicity, "Harm to Human Health," "Harm to the Environment." With respect to the gravity of harm of these violations, a "Pesticide" toxicity value of "1" was assigned at the time of the Complaint, based on the labels and/or advertisements, since the products are presumably "food grade" and, in themselves, not highly toxic. At the time of the initial penalty calculation, a value of "1" was assigned each to "Harm to Human Health" and "Environmental Harm," given the Agency's lack of knowledge of the potential extent of harm the substances in these products could have on human health or the environment. While Dr. Blackburn's testimony arguably could justify a higher assessment for this category, Complainant elects not to depart from the original assessment.

The "Gravity of Misconduct" component under Appendix B of the FIFRA ERP is split into "Compliance History" and "Culpability." With respect to "Compliance History" section of Appendix B, "Compliance History" was assigned a value of zero at the time of the Complaint, based on the absence of any record of a known prior FIFRA enforcement action taken against the Respondent. Finally, "Culpability" was assigned a value of two based on unknown culpability of the Respondent with respect to these

violations. However, as Mr. Bonace testified during the hearing in this matter, had he known of Behnke's discussions with NSF at the time he calculated the original proposed penalty, a higher value would have been assigned for the "Culpability" factor. (March 31 Tr., 0190-0195, 0195-0197 and CX 36, at EPA 0755-56). Again, however, Complainant elects not to depart from its original penalty calculation. Rather, Complainant cites to the evidence of Behnke's communications with NSF, and Respondent's continued violations even after filing of the Complaint, strictly to point out that Respondent's argument that the "Culpability" factor should be assigned a "zero" is contradicted by the evidence, and should be rejected by this Court.

Given the above analysis, a Total Gravity Adjustment Value of five was assigned for each violation. Under Table 3 of the FIFRA ERP, a Total Gravity Adjustment Value of five calls for a reduction of the matrix value by 30%. See FIFRA ERP, p. 22. In this case, each violation was assigned a matrix value of $6,500. Thus, the adjusted penalty for each violation is $4,550.

e. Effect of Penalty on the Person's Ability to Continue in Business.

Section 14(a)(4) of FIFRA requires the Agency to consider the effect of the penalty on the person's ability to continue in business. Through its financial analysis expert, Mr. Mark Ewen of Industrial Economics, Complainant considered the effect of the proposed penalty on Behnke's ability to continue in business. The information considered by EPA to date includes the following: a Dun & Bradstreet Report identifying Behnke Lubricants, Inc.'s, annual sales volume as $ 7,900,000; a Waukesha County Tax Bill for the Behnke facility, which shows that the real estate on which the Behnke facility appears to be located (at the address W134N5373 Campbell Drive,

Menomonee, Wisconsin) has an assessed value of $1,472,400; and the June 2007 Declaration of financial analysis expert Mark Ewen, which offers the opinion that, based on the financial information currently in EPA's possession, "Respondent appears to have sufficient revenues to pay a penalty of $50,050, as proposed in EPA's complaint" (CX 32). On the basis of this information, Complainant determined that no reduction in the calculated penalty based on considerations of the effect of the penalty on Respondent's ability to continue in business is warranted in this case. Moreover, as pointed out above, Respondent has expressly waived any objection to the penalty based on the effect of the penalty on Behnke's ability to continue in business.

For the reasons set forth above, this Court should impose the full proposed penalty of $50,050 for Respondent's violations of FIFRA.

VIII. Conclusion and Prayer for Relief

During hearing, U.S. EPA's expert witness, Mr. Edwards, testified that it was his opinion that Behnke's five lubricants in question were pesticides and required FIFRA registration.

Q. Okay. Then moving on, we really don't have much more to go. Mr. Edwards, in your opinion, based on Respondent's labeling, advertising and marketing claims, what is the intended purpose of the five lubricants we have been discussing?
A. I think it's -- based on the literature and all, that it's clear they're intended to function as lubricants, but they also make antimicrobial claims and, therefore, should be registered as pesticide products.

0361

Q. Okay. Based on your opinion, does the on or in processed food exemption apply in any way to the five products?
A. No, it does not.
Q. And in your opinion -- strike that. In your opinion, if these five antimicrobial lubricants were to be registered under FIFRA, would EPA allow the types of claims that have been made here?
A. Some of the claims might be allowed if there were adequate supporting data that would show that the products performed as the claims indicated. Certainly if they were to come in and apply for registration as a preservative, to be applied to lubricants as a preservative, then they could make that application along with whatever the supporting data are as needed.

Q. Okay. I'm going to direct your attention to Complainant's Exhibit 8b for a second, and it's 249, the second half of that page. Specifically with respect to the statement that says, if a bacteria, yeast or mold colony is already established, FDA/USDA/NSF-approved competitor lubricants will inhibit the growth of the colony, but to actually kill the colony will require a sanitization process or the use of JAX food-grade lubricants which incorporate Micronox technology. Would you allow that claim?
0362
A. We would not allow a sanitization claim without supporting data.
Q. Based on your -- based on the labeling, advertising and marketing claims that have been made by Behnke with respect to the five lubricants, what is your opinion as to whether each of these lubricants should have been registered with FIFRA?
A. Based on the claims on the literature that we discussed, all five products should be registered.

(April 1 Tr., 0360-0362).

Based on the record and the evidence presented during hearing, the U.S. EPA has shown by a preponderance of the evidence that Behnke violated FIFRA on eleven (11) different occasions as alleged in the Complaint.

Further, Mr. Bonace calculated the penalty in accordance with the Enforcement Response Policy for FIFRA (CX 33 and 34), taking into consideration all necessary statutory factors. (See CX 14a, 14b). Further, Mr. Bonace testified at hearing regarding the penalty. (March 31 Tr., 0184-0197). U.S. EPA respectfully submits that the proposed penalty of at least $50,050 must be assessed against Behnke for the violations alleged in the underlying Complaint.

IX. Proposed Findings of Facts

Complainant respectfully requests that this Honorable Court make the following Findings of Fact:

1. On August 3, 2006, an inspector employed by the WDA conducted an inspection under FIFRA at Respondent's establishment to inspect and collect samples of any pesticides packaged, labeled, and/or released for shipment by Respondent and to

collect samples of any containers, labeling and/or advertising literature for such pesticides as authorized under Sections 8 and 9 of FIFRA, 7 U.S.C. §§ 136f and 136g.

2. During the August 3, 2006 inspection, the inspector collected physical samples of **JAX Poly-Guard FG-2** and **JAX Halo-Guard FG-2**, which were packaged, labeled and ready for distribution or sale.

3. During the August 3, 2006 inspection, the inspector also collected sample literature for the following Behnke products: **JAX Poly-Guard FG-2, JAX Poly-Guard FG-LT, JAX Halo-Guard FG-2, JAX Halo-Guard FG-LT,** and **JAX Magna-Plate 74.**

4. During the August 3, 2006 inspection, the inspector also collected invoices showing the shipment of **JAX Poly-Guard FG-2, JAX Poly-Guard FG-LT, JAX Halo-Guard FG-2, JAX Halo-Guard FG-LT**, and **JAX Magna-Plate 74**, which were offered for sale by Respondent.

5. Respondent's literature that was obtained by the inspector on August 3, 2006, for **JAX Poly-Guard FG-2** stated, among other things:

> (A) "Since June 1, 2001, JAX Poly-Guard FG contains Micronox®, providing antimicrobial protection for the product. JAX Micronox® has proven especially effective in protecting JAX Poly-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."
> (B) "Powerful Antimicrobial Performance"
> (C) "Added Step in Microbial Protection Programs"
> (D) The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.

6. Respondent's literature that was obtained by the inspector on August 3, 2006, for **JAX Poly-Guard FG-LT** stated, among other things:

> (A) "Since June 1, 2001, JAX Poly-Guard FG contains Micronox®, providing antimicrobial protection for the product. JAX Micronox® has

proven especially effective in protecting JAX Poly-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."
(B) "Powerful Antimicrobial Performance"
(C) "Added Step in Microbial Protection Programs"
(D) The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.

7. Respondent's literature that was obtained by the inspector on August 3, 2006, for **JAX Halo-Guard FG-2** stated, among other things:

(A) "JAX Halo-Guard FG greases incorporate JAX new, proprietary antimicrobial additive technology, Micronox®, to provide antimicrobial protection for the product. A first in food-grade lubricants, JAX Micronox has proven especially effective in protecting JAX Halo-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."
(B) The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.

8. Respondent's literature that was obtained by the inspector on August 3, 2006, for **JAX Halo-Guard FG-LT** stated, among other things:

(A) "JAX Halo-Guard FG greases incorporate JAX new, proprietary antimicrobial additive technology, Micronox®, to provide antimicrobial protection for the product. A first in food-grade lubricants, JAX Micronox has proven especially effective in protecting JAX Halo-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."
(B) The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.

9. Respondent's literature that was obtained by the inspector on August 3, 2006, for **JAX Magna Plate 74** stated, among other things:

(A) "JAX Magna-Plate 74 incorporates JAX new, proprietary antimicrobial additive technology, Micronox®, for enhanced antimicrobial protection for the product against a wide variety of microbial agents, including yeasts, molds, and gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox® has proven especially effective in protecting the product against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium)."
(B) "JAX Magna-Plate 74 provides three major benefits to food and

beverage processing plants ... Micronox® anti-microbial technology to provide antimicrobial protection for the product..."
(C) "Powerful Antimicrobial Performance"
(D) "Added Step in Microbial Protection Programs"
(E) The literature includes container sizes and part numbers in addition to Respondent's contact information which includes a phone number, facsimile number and Internet address.

10. On November 17, 2006, Respondent's Internet site at www.jax.com stated, among other things:

(A) "With the added benefit of Micronox®, JAX exclusive anti-microbial chemistry which independent testing has proven to be the most effective in the industry, plants can achieve an extra degree of sanitation protection."
(B) "**JAX Poly-Guard FG** grease contains Micronox® the only truly effective, active bacteria control agent in the food grade lubricant industry."
(C) "**JAX Poly-Guard FG** and **Halo-Guard FG** greases contain Mircronox®, the only truly effective, active microbial control agent in the food grade lubricant industry.
(D) "Now contains Micronox® anti-microbial for true 'knockdown' performance against a broad spectrum of microbial contaminants."
(E) "The introduction of JAX exclusive Micronox® Anti-Microbial Technology gives plants in search of tools for added micro-organism control a powerful, extra weapon in their arsenal of protection!"
(F) "As of May 1, 2002 every food grade lubricant in the JAX line incorporates our exclusive Micronox® Anti-Microbial Technology, providing true 'knock-down' performance against a wide range of bacteria and other micro organisms."

11. An Internet site on June 23, 2006, at www.meatpoultry.com features a promotional story on **JAX Magna Plate 74** which states, among other things:

(A) "In an effort to combat Listeria and other harmful microbial agents in air-operated equipment, Behnke Lubricants Inc/JAX has introduced Magna Plate-74 with Micronox®..."
(B) "Magna-Plate 74 contains JAX's Micronox® technology, a revolutionary food-grade antimicrobial agent that provides unsurpassed protection against potentially deadly bacterial contamination such as E-coli, Listeria and Salmonella."
(C) "Magna-Plate 74 provides various benefits to food and beverage processing plants, including: longer bearing and air operated equipment life; Micronox® antimicrobial technology to knockdown and prevent growth in the air system..."
(D) The article goes on to say: "JAX lubrication products are distributed

worldwide. For information about JAX products, consumers can call toll-free 1-800-782-8850, or email requests to info@jax.com."

12. The label on the **JAX Poly-Guard FG-2** container, observed and collected by the inspector on August 3, 2006, states: "Advanced, Anti-Wear NSF H1, Food Machinery Grease with PTFE and Micronox® Antimicrobial," "The bonus is an H1 lubricating grease with Micronox®, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs."

13. The label on the **JAX Halo-Guard FG-2** container, observed and collected by the inspector on August 3, 2006, stated: "JAX HALO-GUARD FG-2 provides Micronox® microbial knockdown performance."

14. On March 8, 2007, U.S.EPA conducted an investigation at American, located at 544 Acme Street, Green Bay, Wisconsin.

15. The purpose of the investigation was to verify if advertising and labeling claims were being made to American by the Respondent relating to Respondent's product **JAX Magna-Plate 74.**

16. During the March 8, 2007 investigation, American gave the inspector copies of two purchase orders showing that American had ordered **JAX Halo-Guard FG-2** and **JAX Magna-Plate 78** from the Respondent, dated December 19, 2006 and March 5, 2007.

17. On March 16, 2007, the inspector received two pieces of literature (via mail) from American which were given to American by the Respondent.

18. The first piece of literature was entitled "American Foods Group, JAX Lube-Guard Program" and included, among other things, the following language:

(A) The packet included literature for **Magna-Plate 78 Fluids** which states, among other things: "Antimicrobial Performance: Both products incorporate JAX new, proprietary antimicrobial additive technology, Micronox™ for enhanced product protection against a wide variety of microbial agents, including yeasts, molds, gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox™ provides significant knockdown performance and has proven especially effective against lysteria (Lysteria monocytogenes), E. coli (Escherichia coli) and salmonella (Salmonella typhimurium) on contact and over extended lubrication intervals."
(B) This literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.
(C) The packet also included literature for **Magna-Plate 74** which states, among other things: "Antimicrobial Performance: JAX Magna-Plate 74 incorporates JAX new, proprietary antimicrobial additive technology, Micronox®, for enhanced antimicrobial protection against a wide variety of microbial agents, including yeasts, molds, and gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox® provides significant knockdown performance and has proven especially effective against lysteria (Lysteria monocytogenes), E. coli (Escherichia coli) and salmonella (Salmonella typhimurium) on contact and over extended lubrication intervals."
(D) This literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.
(E) The packet also included literature for **Halo-Guard FG** which states, "JAX Halo-Guard FG provides Micronox® microbial knockdown performance."

19. The second piece of literature was entitled "JAX Lubricant Guide for Food, Beverage and Drug" and included, among other things, the following language:

(A) A cover letter addressed to the customer which states: "First and foremost is Micronox®, JAX advanced antimicrobial technology that provides immediate and significant knockdown performance on a wide spectrum of microbial contaminants. This development alone is providing HACCP programs a powerful new weapon in their ongoing battle against microorganisms."
(B) The packet also included a sheet entitled "JAX Micronox® Technologies" which describes in detail the enhanced antimicrobial capabilities of the Micronox® additive system including a graph comparing Poly-Guard FG with competitors in efficacy against Listeria, E. Coli, and Salmonella.
(C) The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.

20. On March 29, 2007, the inspector received another piece of literature from American which was given to American by the Respondent.

21. This literature was entitled "Technology Focus, JAX Micronox™ Technology, Introducing Micronox™ Technology in JAX Food-Grade Lubricants for Microbial Knockdown Performance against Listeria, E. coli, Salmonella and other microorganisms" and included, among other things:

> (A) A letter from the Behnke Technical Director entitled: "What is JAX Micronox™ Technology: Re: Antimicrobial Usage in JAX Food-Grade Products."
> (B) Literature for **Poly-Guard Greases** which makes many claims regarding its antimicrobial capabilities and performance due to Micronox™.
> (C) Literature for **Magna Plate 78** which makes many claims regarding its antimicrobial capabilities and performance due to Micronox™.
> (D) Literature entitled "Plant Microbial Knockdown Results" which includes references to **JAX Poly-Guard FG-2** and its antimicrobial features.
> (E) Literature entitled "Major Food Processor Lab Test Results" which also makes references to **JAX Poly-Guard FG-2** and its antimicrobial features.
> (F) Literature entitled "Independent Lab Results" which also makes references to **JAX Poly-Guard FG-2** and its antimicrobial features.
> (G) Literature entitled "Food Industry Firsts" that states, among other things: "The first effective food-grade antimicrobial additive for lubricants with knockdown capabilities, effectively partnering lubricants into plant sanitation programs."
> (H) The literature also included contact information for Respondent including Respondent's phone number, facsimile number, Internet address, distributor information and product ordering options.

22. On March 8, 2006, U.S. EPA conducted an investigation at Badger, located at 3451 Johnson Avenue, Plover, Wisconsin.

23. The purpose of the investigation was to verify if advertising and labeling claims were being made to Badger by the Respondent relating to Respondent's products **JAX Halo-Guard FG-2** and **JAX Poly-Guard FG-2**.

24. During the investigation on March 8, 2007, the inspector was taken to a supply area by Badger employees.

25. The inspector observed four boxes, each containing ten 14-ounce cartridge tubes of **JAX Poly-Guard FG-2** in the storage area.

26. The inspector viewed a single tube from each of the four boxes in the storage room.

27. All four cartridge tubes bore the same language: "Advanced, Anti-Wear NSF H1, Food Machinery Grease with PTFE and Micronox® Antimicrobial," "The bonus is an H1 lubricating grease with Micronox®, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs."

28. The four tubes of **JAX Poly-Guard FG-2** observed by the inspector at Badger were identical to the physical sample of **JAX Poly-Guard FG-2** that was obtained on August 3, 2006 during the Behnke inspection.

29. During the visit on March 8, 2007, Badger also provided the inspector with a brochure that was given to Badger by Respondent.

30. The brochure was entitled "Food Grade Lubricants with Micronox™."

31. The brochure included a document entitled "What is JAX Micronox™ Technology? Re: Antimircrobial Usage in JAX Food-Grade Products" and described the antimicrobial capabilities of the Micronox™ technology found in Respondent's food grade lubricants.

32. The brochure also included tables and a graph illustrating the "antimicrobial properties" of **Poly-Guard FG-2** "antimicrobial grease" and its efficacy against Listeria,

E. coli and Salmonella.

33. The literature also included contact information for Respondent including Respondent's phone number, facsimile number, Internet, distributor information and product ordering options.

34. During the March 8, 2007 investigation, Badger gave the inspector a copy of a shipping record from Respondent to Badger for **JAX Halo-Guard FG-2** and **JAX Poly-Guard FG-2**, with a shipment date of September 18, 2006.

35. On March 7, 2006, the State of Minnesota Department of Agriculture conducted an inspection at Jennie-O, located at 1530 30th Street SW, Wilmar, Minnesota.

36. The purpose of the inspection was to verify if advertising and labeling claims were being made to Jennie-O by the Respondent relating to Respondent's product **JAX Halo-Guard FG-LT**.

37. During the March 7, 2007 inspection, the inspector viewed and photographed a cartridge tube of **JAX Halo-Guard FG-LT**.

38. The labeling on the tube stated "JAX Halo-Guard FG-LT provides Micronox® microbial knockdown performance"

39. During the investigation, Jennie-O confirmed that the **JAX Halo-Guard FG-LT** was ordered on or about June 2006.

40. On March 7, 2007, U.S. EPA conducted an investigation at Perlick, located at 8300 West Good Hope Road, Milwaukee, Wisconsin.

41. The purpose of the investigation was to verify if advertising and labeling claims were being made to Perlick by the Respondent relating to Respondent's product, **JAX Poly-Guard FG-2**.

42. During the investigation on March 7, 2007, the inspector viewed a 14-ounce cartridge of **JAX Poly-Guard FG-2**.

43. The cartridge included the following language: "Advanced, Anti-Wear NSF H1, Food Machinery Grease with PTFE and Micronox® Antimicrobial," "The bonus is an H1 lubricating grease with Micronox®, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs."

44. The cartridge of **JAX Poly-Guard FG-2** observed by the inspector at Perlick was identical to the physical sample of **JAX Poly-Guard FG-2** that was obtained on August 3, 2006 during the Benhke inspection.

45. On March 8, 2007, U.S. EPA conducted an investigation at Sara Lee, located at N3620 County Road D, New London, Wisconsin.

46. The purpose of the investigation was to verify if advertising and labeling claims were being made to Sara Lee by the Respondent relating to Respondent' product **JAX Magna-Plate 74**.

47. During the investigation on March 8, 2007, the inspector viewed a 14-ounce cartridge of **JAX Poly-Guard FG-2**.

48. The cartridge included the following language : "Advanced, Anti-Wear NSF H1, Food Machinery Grease with PTFE and Micronox® Antimicrobial," "The bonus is an H1 lubricating grease with Micronox®, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs."

49. The cartridge of **JAX Poly-Guard FG-2** observed by the inspector at Sara Lee was identical to the physical sample of **JAX Poly-Guard FG-2** that was obtained on August 3, 2006 during the Benhke inspection.

50. During the March 8, 2007 investigation, Sara Lee gave the inspector a copy of a purchase order from Sara Lee to Badger for the purchase of **JAX Poly-Guard FG-2**, with an order date of February 12, 2007.

51. On March 7, 2007, U.S. EPA conducted an investigation at Seneca, located at 640 Caughlin Road, Clyman, Wisconsin.

52. The purpose of the investigation was to verify if advertising and labeling claims were being made to Seneca by the Respondent relating to Respondent's products **JAX Halo-Guard FG-2**.

53. During the investigation on March 7, 2007, Seneca provided the inspector with information sheets that Seneca had received from Behnke.

54. The first information sheet was entitled: "JAX MAGNA-PLATE 72, USDA H1-AUTHORIZED AIR LINE LUBE WITH ANTIRUST AND ANTIWEAR ADDITIVES NOW WITH MICRONOX® ANTIMICROBIAL TECHNOLOGY" and included the following language:

"Antimicrobial Performance: JAX MAGNA-PLATE 72 incorporates JAX new, proprietary antimicrobial additive technology, Micronox®, for enhanced antimicrobial protection against a wide variety of microbial agents, including yeast, molds, gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox® provides significant knockdown performance and has proven especially effective against (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

55. The second information sheet was entitled:

"JAX MAGNA-PLATE 78 USDA H1-AUTHORIZED EXTREME - PRESSURE FOOD MACHINERY OIL WITH ENHANCED ANTIWEAR PROPERTIES NOW WITH

MICRONOX® ANTIMICROBIAL TECHNOLOGY" and includes the following language "Antimicrobial Performance: JAX MAGNA-PLATE 78 incorporates JAX new, proprietary antimicrobial additive technology, Micronox™, for enhanced antimicrobial protection against a wide variety of microbial agents, including yeast, molds, gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox™ provides significant knockdown performance and has proven especially effective against (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

56. The third information sheet was entitled: "HALO-GUARD FG GREASES" and included the following language: "JAX Halo-Guard FG provides Micronox® microbial knockdown performance."

57. The final information sheet was entitled "JAX POLY-GUARD FG, A REVOLUTIONARY USDA-H1 FOOD-GRADE GREASE W/PTFE FOR LUBRICATION OF HIGH-SPEED/HIGH-TEMP FOOD AND BEVERAGE PROCESSING MACHINERY NOW WITH MICRONOX® ANTIMICROBIAL TECHNOLOGY" and included the following language:

"Antimicrobial Performance: JAX POLY-GUARD FG incorporates JAX new, proprietary antimicrobial additive technology, Micronox®, for enhanced antimicrobial protection against a wide variety of microbial agents, including yeast, molds, gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox® provides significant knockdown performance and has proven especially effective against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

58. On or about March 12, 2007, Seneca forwarded an electronic mail message to U.S. EPA, that had been sent to Seneca by Behnke on or about October 26, 2006.

59. The October 26, 2006 electronic mail message from Behnke to Seneca, which was entitled "Halo Guard and Poly Guard Data Sheets" had two data sheets attached to it for **JAX Halo-Guard FG Series** and **JAX Poly-Guard Series Greases.**

60. The first information sheet was entitled "HALO-GUARD FG GREASES" and included the following language:

"Antimicrobial Performance: JAX Halo-Guard FG Greases incorporate JAX new, proprietary antimicrobial additive technology, Micronox®, to provide antimicrobial protection for the product. A first in food-grade lubricants, JAX Micronox® has proven especially effective in protecting JAX Halo-Guard FG Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

61. The second information sheet was entitled "POLY-GUARD FG-LT, FG-2" and included the following language:

"Since June 1, 2001 JAX Poly-Guard FG contains Micronox®, providing antimicrobial protection for the product. JAX Micronox® has proven especially effective in protecting JAX Poly-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

62. During the March 7, 2007 investigation, Seneca gave the inspector copies of seven shipping records from Respondent to Seneca for **JAX Halo-Guard FG-2, JAX Halo-Guard FG-LT,** and **JAX Magna-Plate 78**.

63. On March 19, 2007, U.S. EPA received a copy of a brochure from KHS located in Waukesha, Wisconsin.

64. The back cover of the brochure is marked "JAX Products Distributed by: Behnke Lubricants, Inc. - JAX" and included Respondent's phone and facsimile numbers in Menomonee Falls, Wisconsin and Sacramento, California.

65. The brochure is entitled "JAX: Lubricant Guide For Food, Beverage, Drug & Cosmetic Processing & Manufacturing."

66. The brochure includes a letter from Respondent to its customers which included the following language: "Micronox®, JAX advanced antimicrobial additive technology that provides immediate and significant knockdown performance on a wide spectrum of microbial contaminants. This development alone is providing HACCP programs a powerful weapon in their ongoing battle against microorganisms." "JAX

Poly-Guard® FG is a new concept in food-grade greases, providing the highest level of antiwear performance of any competitor, and the benefits of Micronox®."

67. The brochure included a table of contents which included a section entitled "Micronox® Antimicrobial Technology."

68. The "Micronox® Antimicrobial Technology" section describes in detail the enhanced antimicrobial capabilities of Micronox® technology.

69. On June 9, 2006, Respondent's internet site at www.jax.com stated, among other things:

> (A) "The introduction of JAX exclusive Micronox® Anti-Microbial Technology gives plants in search of tools for added micro organism control a powerful, extra weapon in their arsenal of protection!"
> (B) "JAX Poly-Guard FG and Halo-Guard FG greases contain Micronox®, the only truly effective, active microbial control agent in the food grade lubricant industry."
> (C) "As of May 1, 2002 every food grade lubricant in the JAX Line incorporates our exclusive Micronox® Anti-Microbial Tecnology, providing true 'knock-down' performance against a wide range of bacteria and other micro organisms!"
> (D) "With the added benefit of Micronox®, JAX exclusive anti-microbial chemistry which independent testing has proven to be the most effective in industry, plants can achieve an extra measure of sanitation protection"
> (E) "JAX Poly-Guard FG grease contains Micronox® the only truly effective, active bacteria control agent in the food grade lubricant industry"
> (F) "Poly-Guard FG-2, FG-LT... Now contains Micronox® anti-microbial for true 'knock-down' performance against a broad spectrum of microbial contaminants."

70. On February 26, 2007, Respondent's internet site at www.jax.com stated, among other things, continued to make many of the same claims that were found on its website on June 9, 2006.

71. On March 21, 2007, the Internet contained many websites that continued to advertise JAX Micronox as having antimicrobial properties. These sites included, but are not limited to:

www.uark.edu/depts/ifse/ofpa/exhibits.htm
www.allbusiness.com/management/business-support-services/669676-1.html
http://milwaukee.bizjournals.com/Milwaukee/stories/2001/11/19/smallb1.html
www.jax.fr/pages; www.powercontrolresources.com/lub.html
https://packexpo2006.bdmetrics.com/Portal/ViewCompany.aspx?id=1876571
www.foodproc.com/ad-jax.shtml
www.ibtinc.com/primemover/archive/PM200507/lub01.html
www.lubrepolo.com/GGAlimenticio/
www.jax.com/press release/pr>halo-fg.html
www.jax.com/press_releases/pr_bottom7.html
www.jax.com/fram_pr.html
www.meatequip.com/supplierad/jax.htm
www.foodengineeringmag.com/CDA/Archives/543b8f4ab52f8010VgnVCM100000f932a8c0
www.gissa.com/en/jax.htm
www.ahi.dk/jax/micronox.htm
www.foodengineeringmag.com
www.foodengineeringmag.com/FE/2006/10/Files/PDFs/FEX/006p_092.pdf
http://filesibnpmedia.com/FE/Protected/Files/PDF/FEX1005p_110.pdf
www.foodengineeringmag.com/FE/2005/06/Files/PDFs/behnke.pdf
www.foodengineeringmag.com/FE/Home/Files/PDFs/FEX0107_149.pdf
www.clfp.com/03EXPO/exhibit/CoDescriptions.pdf.

72. On or about March 3, 2006, Respondent distributed or sold **JAX Poly-Guard FG-2** to Perlick located in Milwaukee, Wisconsin.

73. On or about June 15, 2006, Respondent distributed or sold **JAX Poly-Guard FG-2** to Badger located in Plover, Wisconsin.

74. On or about September 18, 2006, Respondent distributed or sold **JAX Poly-Guard FG- 2** to Badger in Plover, Wisconsin.

75. On or about August 3, 2006, Respondent distributed or sold **JAX Poly-Guard FG-2** by having **JAX Poly-Guard FG-2** packaged, labeled and ready for shipment or sale at its location of W134 N5373 Campbell Drive, Menomonee Falls, Wisconsin.

76. On or about February 11, 2005, Respondent distributed or sold **JAX Poly-Guard FG-LT** to Faribalt Foods located in Cokato, Minnesota.

77. On or about June 6, 2006, Respondent distributed or sold **JAX Poly-Guard FG-LT** to Pepsi Cola located in Sacramento, California.

78. On or about March 14, 2006, Respondent distributed or sold **JAX Halo-Guard FG-2** to B-Way Corporation located in Sturtevant, Wisconsin.

79. On or about June 15, 2006, Respondent distributed or sold **JAX Halo-Guard FG-2** to Badger located in Plover, Wisconsin.

80. On or about July 14, 2006, Respondent distributed or sold **JAX Halo-Guard FG-2** to Seneca located in Clyman, Wisconsin.

81. On or about December 19, 2006, Respondent distributed or sold **JAX Halo-Guard FG-2** to American in Green Bay, Wisconsin.

82. On or about September 18, 2006, Respondent distributed or sold **JAX Halo-Guard FG-2** to Badger in Plover, Wisconsin.

83. On or about October 23, 2006, Respondent distributed or sold **JAX Halo-Guard FG-2** to Seneca in Clyman, Wisconsin.

84. On or about October 18, 2006, Respondent distributed or sold **JAX Halo-Guard FG-2** to Seneca in Clyman, Wisconsin.

85. On or about August 3, 2006, Respondent distributed or sold **JAX Halo-Guard FG-2** by having **JAX Halo-Guard FG-2** packaged, labeled and ready for shipment or sale at its location of W134 N5373 Campbell Drive, Menomonee Falls, Wisconsin.

86. On or about April 7, 2006, Respondent distributed or sold **JAX Halo-Guard FG-LT** to KHS located in Waukesha, Wisconsin.

87. On or about June 27, 2006, Respondent distributed or sold **JAX Halo-**

Guard FG-LT to Jennie-O Turkey Store (Jennie-O) located in Willmar, Minnesota.

89. On or about October 17, 2006, Respondent distributed or sold **JAX Halo-Guard FG-LT** to Seneca in Clyman, Wisconsin.

88. On or about September 29, 2006, Respondent distributed or sold **JAX Halo-Guard FG-LT** to Seneca in Clyman, Wisconsin.

89. On or about September 7, 2006, Respondent distributed or sold **JAX Halo-Guard FG-LT** to Seneca in Clyman, Wisconsin.

90. On or about August 18, 2006, Respondent distributed or sold **JAX Halo-Guard FG-LT** to Seneca in Clyman, Wisconsin.

91. On or about July 11, 2006, Respondent distributed or sold **JAX Magna-Plate 74** to Sara Lee located in New London, Illinois.

92. On or about March 3, 2006, Respondent distributed or sold **JAX Magna-Plate 74** to American in Green Bay, Wisconsin.

93. On or about December 19, 2006, Respondent distributed or sold **JAX Magna-Plate 78** to American in Green Bay, Wisconsin.

94. On or about March 5, 2007, Respondent distributed or sold **JAX Magna-Plate 78** to American in Green Bay, Wisconsin.

95. On or about March 3, 2006, Respondent distributed or sold **JAX Magna-Plate 78** to American in Green Bay, Wisconsin.

96. On or about September 7, 2006, Respondent distributed or sold **JAX Magna-Plate 78** to Seneca in Clyman, Wisconsin.

97. Behnke distributed or sold **JAX Poly-Guard FG-2, JAX Magna Plate-74** and **JAX Magna-Plate 78** to American on many occasions between May 29, 2002 and

May 7, 2007.

98. Complainant obtained a Dun & Bradstreet, Inc., "Dun's Market Identifiers" report for Behnke Lubricants Inc., dated March 30, 2006, which estimated annual sales of $7,900,000.

X. Proposed Conclusions of Law

Complainant respectfully requests that this Honorable Court make the following Conclusions of Law:

1. Respondent is a "person" as defined at Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

2. Behnke is a corporation organized under the laws of the State of Wisconsin with a place of business located at W134 N5373 Campbell Drive, Menomonee Falls, Wisconsin 53051.

3. Respondent's literature obtained at the August 3, 2006 inspection claims, states or implies that **JAX Poly-Guard FG-2** is a pesticide.

4. Respondent's literature for **JAX Poly-Guard FG-2** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

5. Respondent's internet site on November 17, 2006 at www.jax.com claims, states or implies that **JAX Poly-Guard FG-2** is a pesticide.

6. Respondent's internet site on November 17, 2006, for **JAX Poly-Guard FG-2** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

7. The label on the **JAX Poly-Guard FG-2** container claims, states or implies that JAX Poly-Guard FG-2 is a pesticide.

8. **JAX Poly-Guard FG-2** is a pesticide as defined by Section 2(u) of FIFRA,

7 U.S.C. § 136(u), and 40 C.F.R. §152.15(a)(1).

9. **JAX Poly-Guard FG-2** is not registered as a pesticide as required by Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).

10. Respondent's literature obtained at the August 3, 2006 inspection claims, states or implies that **JAX Poly-Guard FG-LT** is a pesticide.

11. Respondent's literature for **JAX Poly-Guard FG-LT** constitute an advertisement as referenced in 40 C.F.R. § 168.22(a).

12. Respondent's Internet site on November 17, 2006 at www.jax.com claims, states or implies that **JAX Poly-Guard FG-LT** is a pesticide.

13. Respondent's internet site on November 17, 2006, for **JAX Poly-Guard FG-LT** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

14. **JAX Poly-Guard FG-LT** is a pesticide as defined by Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. §152.15(a)(1).

15. **JAX Poly-Guard FG-LT** is not registered as a pesticide as required by Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).

16. Respondent's literature obtained at the August 3, 2006 inspection claims, states or implies that **JAX Halo-Guard FG-2** is a pesticide.

17. Respondent's literature for **JAX Halo-Guard FG-2** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

18. Respondent's internet site on November 17, 2006, at www.jax.com claims, states or implies that **JAX Halo-Guard FG-2** is a pesticide.

19. Respondent's Internet site on November 17, 2006, for **JAX Halo-Guard FG-2** constitutes advertisements as defined in 40 C.F.R. § 168.22(a).

20. The label on the **JAX Halo-Guard FG-2** container claims, states or implies that **JAX Halo-Guard FG-2** is a pesticide.

21. **JAX Halo-Guard FG-2** is a pesticide as defined by Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. §152.15(a)(1).

22. **JAX Halo-Guard FG-2** is not registered as a pesticide as required by Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).

23. Respondent's literature obtained at the August 3, 2006 inspection claims, states or implies that **JAX Halo-Guard FG-LT** is a pesticide.

24. Respondent's literature for **JAX Halo-Guard FG-LT** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

25. Respondent's internet site on November 17, 2006, at www.jax.com claims, states or implies that **JAX Halo-Guard FG-LT** is a pesticide.

26. Respondent's internet site on November 17, 2006, for **JAX Halo-Guard FG-LT** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

27. **JAX Halo-Guard FG-LT** is a pesticide as defined by Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.15(a)(1).

28. **JAX Halo-Guard FG-LT** is not registered as a pesticide as required by Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).

29. Respondent's literature obtained at the August 3, 2006 inspection claims, states or implies that **JAX Magna-Plate 74** is a pesticide.

30. Respondent's literature for **JAX Magna-Plate 74** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

31. The Internet site on June 23, 2006, at www.meatpoultry.com claims, states or

implies that **JAX Magna-Plate 74** is a pesticide.

32. The June 23, 2006 Internet site at www.meatpoultry.com, for **JAX Magna Plate-74** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

33. Respondent's Internet site at www.jax.com , on November 17, 2006 claims, states or implies that **JAX Magna-Plate 74** is a pesticide.

34. The November 17, 2006 Internet site at www.jax.com, for **JAX Magna Plate-74** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

35. **JAX Magna-Plate 74** is a pesticide as defined by Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and 40 C.F.R. § 152.15(a)(1).

36. **JAX Magna-Plate 74** is not registered as a pesticide as required by Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).

37. Respondent's literature received by U.S. EPA from American on March 16, 2007 claims, states or implies that **Halo-Guard FG-2** is a pesticide.

38. Respondent's literature received by U.S. EPA from American on March 16, 2007 claims, states or implies that **JAX Magna-Plate 74** is a pesticide.

39. Respondent's literature received by U.S. EPA from American on March 16, 2007 claims, states or implies that **JAX Magna-Plate 78** is a pesticide.

40. Respondent's literature received by U.S. EPA from American on March 16, 2007 claims, states or implies that **JAX Poly-Guard FG-2** is a pesticide.

41. Respondent's literature received by U.S. EPA from American on March 29, 2007 claims, states or implies that **Halo-Guard FG-2** is a pesticide.

42. Respondent's literature received by U.S. EPA from American on March 29, 2007 claims, states or implies that **JAX Magna-Plate 74** is a pesticide.

43. Respondent's literature received by U.S. EPA from American on March 29, 2007 claims, states or implies that **JAX Magna-Plate 78** is a pesticide.

44. Respondent's literature received by U.S. EPA from American on March 29, 2007 claims, states or implies that **JAX Poly-Guard FG-2** is a pesticide.

45. Respondent's literature found at American for **JAX Magna-Plate 74** constitutes advertisements as defined in 40 C.F.R. § 168.22(a).

46. Respondent's literature found at American for **JAX Magna-Plate 78** constitutes advertisements as defined in 40 C.F.R. § 168.22(a).

47. Respondent's literature found at American for **JAX Poly-Guard FG-2** constitutes advertisements as defined in 40 C.F.R. § 168.22(a).

48. **JAX Magna-Plate 78** is a pesticide as defined by Section 2(u) of FIFRA, 7 U.S.C. § 136(u) and 40 C.F.R. § 152.15(a)(1).

49. **JAX Magna-Plate 78** is not registered as a pesticide as required by Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).

50. Respondent's literature found at Badger claims, states or implies that **JAX Poly-Guard FG-2** is a pesticide.

51. Respondent's literature found at Badger for **JAX Poly-Guard FG-2** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

52. The literature at Seneca claims, states or implies that **JAX Magna-Plate 74** is a pesticide.

53. Respondent's literature found at Seneca for **JAX Magna-Plate 74** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

54. The literature at Seneca claims, states or implies that **JAX Magna-Plate 78** is

a pesticide.

55. Respondent's literature found at Seneca for **JAX Magna-Plate 78** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

56. The literature at Seneca claims, states or implies that **JAX Halo-Guard FG Greases** is a pesticide.

57. Respondent's literature for **JAX Halo-Guard FG Greases** constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).

58. The literature at Seneca claims, states or implies that **JAX Poly-Guard FG** is a pesticide

59. Respondent's literature for **JAX Poly-Guard FG** constitutes an advertisements as referenced in 40 C.F.R. § 168.22(a).

60. All the internet sites listed above, claim, state or imply that Respondent's products containing Micronox® technology are pesticides.

61. All the internet sites listed in above, constitute advertisements, as referenced in 40 C.F.R. § 168.22(a).

62. The word "micronox" claims, states or implies that Respondent's products containing Micronox antimicrobial technology are pesticides.

63. Respondent distributed, offered for sale, or sold **JAX Poly-Guard FG-2** on or about August 3, 2006 in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

64. Respondent distributed, offered for sale, or sold **JAX Halo-Guard FG-2** on or about August 3, 2006, in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

65. Respondent distributed, offered for sale, or sold **JAX Halo-Guard FG-2** on or about December 19, 2006 to American, in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

66. Respondent distributed, offered for sale, or sold **JAX Magna-Plate 78** on or about December 19, 2006 to American, in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

67. Respondent distributed, offered for sale, or sold **JAX Magna-Plate 78** on or about March 5, 2007 to American, in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

68. Respondent distributed, offered for sale, or sold **JAX Magna-Plate 78** on or about March 3, 2006 to American, in violation of Section Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

69. Respondent distributed, offered for sale, or sold **JAX Magna-Plate 74** on or about March 3, 2006 to American, in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

70. Respondent distributed, offered for sale, or sold **JAX Poly-Guard FG-2** on or about September 18, 2006 to Badger, in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

71. Respondent distributed, offered for sale, or sold **JAX Poly-Guard FG-2** on or about June 15, 2006 to Badger, in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

72. Respondent distributed, offered for sale, or sold **JAX Halo-Guard FG-LT** on or about June 27, 2006 to Jennie-O, in violation Sections 3(a) and 12(a)(1)(A) of

FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

73. Respondent distributed, offered for sale, or sold **JAX Poly-Guard FG-2** on or about March 3, 2006 to Perlick, in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

XI. Proposed Penalty

Complainant further respectfully requests that this Honorable Court impose the following penalty on Respondent for its violations of FIFRA:

Based on the facts presented above, the gravity of the violations alleged herein, the size of Respondent's business, and Respondent's ability to continue in business in light of the proposed penalty, Respondent is assessed the following civil penalty for the violations alleged in this Complaint:

Count I

Distribution/Sale of Unregistered
Pesticide Product. $4,550

Count II

Distribution/Sale of Unregistered
Pesticide Product $4,550

Count III

Distribution/Sale of Unregistered
Pesticide Product. $4,550

Count IV

Distribution/Sale of Unregistered
Pesticide Product $4,550

Count V

Distribution/Sale of Unregistered
Pesticide Product. $4,550

Count VI

Distribution/Sale of Unregistered
Pesticide Product. $4,550

Count VII

Distribution/Sale of Unregistered
Pesticide Product $4,550

Count VIII

Distribution/Sale of Unregistered
Pesticide Product. $4,550

Count IX

Distribution/Sale of Unregistered
Pesticide Product. $4,550

Count X

Distribution/Sale of Unregistered
Pesticide Product $4,550

Count XI

Distribution/Sale of Unregistered
Pesticide Product. $4,550

Total Proposed Civil Penalty $50,050

XII. Conclusion

For the reasons set forth above, Complainant respectfully requests that this Honorable Court find Respondent liable for the violations alleged in the Complaint, and impose the penalty proposed in the Complaint.

Respectfully Submitted,

June 24, 08

Nidhi K. O'Meara
James J. Cha
Erik H. Olson
Associate Regional Counsels
U.S. EPA, Region 5

Date

In the Matter of Behnke Lubricants, Inc.

Docket No. FIFRA-05-2007-0025

CERTIFICATE OF SERVICE

I hereby certify that the original and one true, accurate and complete copy of Complainant's Post-Hearing Brief were filed with the Regional Hearing Clerk, U.S. EPA, Region 5, on the date indicated below, and that true, accurate and complete copies of Complainant's Post-Hearing Brief were served on the Honorable Barbara Gunning, Administrative Law Judge (service by Pouch Mail), and Mr. Bruce McIlnay, Esq., Counsel for Respondent Behnke Lubricants, Inc. (service by Federal Express), on the date indicated below:

Dated in Chicago, Illinois, this 25 day of June, 2008.

Patricia Jeffries-Harwell
Legal Technician
Office of Regional Counsel
U.S. EPA, Region 5