

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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ENVIR. APPEALS BOARD

IN THE MATTER OF)
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BEHNKE LUBRICANTS, INC.,) DOCKET NO. FIFRA-05-2007-0025
)
)
RESPONDENT)
)

INITIAL DECISION

Pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended, 7 U.S.C. § 136l(a), Respondent Behnke Lubricants, Inc. is assessed a civil administrative penalty of \$55,055 for violations of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).

Issued: December 30, 2008

Before: Barbara A. Gunning
Administrative Law Judge

Appearances:

For Complainant: Nidhi K. O'Meara
James J. Cha
Erik H. Olson
U.S. EPA, Region 5
77 West Jackson Boulevard
Chicago IL 60604

For Respondent: Bruce A. McIlnay
Linda S. Isnard
Joseph F. Kirgues
McIlnay & Button
1150 Washington Street
Grafton, WI 53024

I. PROCEDURAL HISTORY

This civil administrative penalty action arises under the authority of Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended, 7 U.S.C. § 136l(a). This proceeding is governed by 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. part 22.

On May 7, 2007, Complainant United States Environmental Protection Agency ("the EPA"), Region V ("Complainant" or "the Region"), filed an eleven-count Complaint and Notice of Opportunity for Hearing ("Complaint") against Behnke Lubricants, Inc. ("Respondent" or "Behnke") pursuant to Section 14(a) of FIFRA. The Complaint alleges that on eleven different occasions, Respondent distributed, offered for sale, 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). The Region proposes a civil administrative penalty of \$50,050.

On June 8, 2007, Respondent filed its Answer and Request for a Hearing ("Answer"). Respondent listed what it identifies as seven affirmative defenses in its Answer, claiming: (1) Behnke's products are not "pesticides" within the meaning of 7 U.S.C. § 136(u); (2) Behnke's products do not contain a "pesticide" as defined by 7 U.S.C. § 136(u); (3) Behnke's products are not "antimicrobial pesticides" within the meaning of 7 U.S.C. § 136(mm); (4) Behnke's products are not "pesticide chemicals" within the meaning of 21 U.S.C. § 321(q)(1)(A); (5) Behnke's products are "food additives" pursuant to 21 U.S.C. § 321(s) that are approved as lubricants with incidental food contact pursuant to 21 U.S.C. § 178.3570, a regulation promulgated pursuant to 21 U.S.C. § 348(a), and as such Behnke's products are strictly regulated by the Food and Drug Administration ("FDA") pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act ("FFDCA"); (6) the intended use of Behnke's products is to protect components of equipment in food and beverage manufacturing plants from wear, corrosion, oxidation, and heat, so Behnke's products are formulated to protect themselves, by resisting internal degradation, from contaminants found in food processing environments; and (7) Behnke's products are not intended for a pesticidal purpose as set forth in 40 C.F.R. § 152.15, because a "pest" as defined in 40 C.F.R. § 152.5 does not include the microorganisms on or in processed food to which Behnke's products are exposed. Answer at 27-28.

Pursuant to the undersigned's Prehearing Order, entered June 27, 2007, Complainant submitted its Prehearing Exchange on October 9, 2007, Respondent submitted its Prehearing Exchange on November 15, 2007, and on November 19, 2007, Complainant submitted its Rebuttal Prehearing Exchange. Respondent filed a Supplemental Prehearing Exchange on December 17, 2007, and Complainant filed its Supplemental Prehearing Exchange on December 26, 2007. Complainant filed its Third Supplemental Prehearing Exchange on February 27, 2008 and its Fourth Supplemental Prehearing Exchange on March 12, 2008 and Respondent filed its Second Supplemental Prehearing Exchange on March 13, 2008. Finally, Complainant's Fifth Supplemental Prehearing Exchange was filed on March 19, 2008.

On January 16, 2008, Complainant filed a Motion to Strike Affirmative Defenses and Motion to Compel Discovery ("Motion to Strike" and "Motion to 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, Complainant filed a Motion for Accelerated Decision on Liability and on Affirmative Defenses ("Motion for Accelerated Decision"). On February 21, 2008, Respondent filed a Response to Complainant's Motion for Accelerated Decision. On March 5, 2008, this Tribunal 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. The March 5, 2008 Order is incorporated herein by reference (Attachment A).

On March 7, 2008, the parties filed a set of Joint Stipulated Facts ("Joint Stipulations").

On March 31, 2008, this Tribunal presided over a four day evidentiary hearing in this matter in Waukesha County, Wisconsin. Both parties were present at the hearing and had an opportunity to put forward evidence and cross-examine witnesses.

Complainant filed a Post-Hearing Brief on June 25, 2008 and Respondent filed its Post-Hearing Brief and Respondent's Proposed Findings of Fact and Conclusions of Law on June 26, 2008. Complainant's Reply to Respondent's Post-Hearing Brief was filed on July 14, 2008 and Respondent's Reply Brief was filed on July 16, 2008.

All Orders previously entered in this proceedings are incorporated by reference into this Initial Decision. For the reasons previously stated and discussed below, having fully considered the record in the case, the arguments of counsel and Respondent, being fully advised, I find Respondent to be in violation of FIFRA and its implementing regulations as alleged in Counts 1 through 11 of the Complaint. For these violations, Respondent shall pay a civil administrative penalty in the amount of \$ 55,055.

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Respondent is a "person" as defined in 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. Eric J. Peter is the president of Behnke.
4. Behnke manufactures JAX® branded lubricants for industrial uses and employs approximately 50 people.

5. A significant percentage of Behnke's business is the sale of lubricants deemed acceptable by NSF International ("NSF") as lubricants with incidental food contact (H1) for use in lubricating and protecting mechanical equipment used in the food processing and bottling industries.
6. For food grade applications, Behnke's lubricant formulations must be FDA compliant for incidental food contact. This requires that the additives and chemistry of the finished product be within the tolerances required under 21 C.F.R. § 178.3570. Behnke must then certify this compliance directly to the customer or through a third-party laboratory, such as NSF.
7. On August 3, 2006, Mr. Jeffrey Saatkamp, an inspector employed with the Wisconsin Department of Agriculture, Trade and Consumer Protection ("WDA") conducted an inspection under FIFRA at Respondent's Menomonee Falls 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.
8. During the August 3, 2006 inspection, Mr. Saatkamp collected physical samples of JAX Poly-Guard FG-2 and JAX Halo-Guard FG-2, which were packaged, labeled, and ready for shipment or sale.
9. During the August 3, 2006 inspection, Mr. Saatkamp also collected sample literature for the following 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.
10. During the August 3, 2006 inspection, Mr. Saatkamp 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.
11. Respondent's literature 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.

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. Respondent's literature obtained at the August 3, 2006 inspection claims, states or implies that JAX Poly-Guard FG-2 is a pesticide.
14. Respondent's literature for JAX Poly-Guard FG-2 constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).
15. The label on the JAX Poly-Guard FG-2 container claims, states or implies that JAX Poly-Guard FG-2 is a pesticide.
16. 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).
17. JAX Poly-Guard FG-2 is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).
18. On or about March 3, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 to Perlick Corporation ("Perlick") located in Milwaukee, Wisconsin.
19. On or about June 15, 2006, and on or about September 18, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 to Badger Plastics & Supply, Inc. ("Badger") located in Plover, Wisconsin.
20. 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.
21. Respondent's literature 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.

22. Respondent's literature obtained at the August 3, 2006 inspection claims, states or implies that JAX Poly-Guard FG-LT is a pesticide.
23. Respondent's literature for JAX Poly-Guard FG-LT constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).
24. 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).
25. 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).
26. Respondent's literature 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 Poly-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.
27. The label on 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."
28. Respondent's literature obtained at the August 3, 2006 inspection, claims, states or implies that JAX Halo-Guard FG-2 is a pesticide.
29. Respondent's literature for JAX Halo-Guard FG-2 constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).
30. The label on the JAX Halo-Guard FG-2 container claims, states or implies that JAX Halo-Guard FG-2 is a pesticide.

31. 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).
32. JAX Halo-Guard FG-2 is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).
33. 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.
34. Respondent's literature 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.
35. Respondent's literature obtained at the August 3, 2006 inspection claims, states or implies that JAX Halo-Guard FG-LT is a pesticide.
36. Respondent's literature for JAX Halo-Guard FG-LT constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).
37. 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).
38. JAX Halo-Guard FG-LT is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).
39. 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.
40. Respondent's literature 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, propriety 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.

41. Respondent's literature obtained at the August 3, 2006 inspection claims, states, or implies that JAX Magna-Plate 74 is a pesticide.
42. Respondent's literature for JAX Magna-Plate 74 constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).
43. 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).
44. JAX Magna-Plate 74 is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).
45. On or about March 3, 2006, Respondent distributed or sold JAX Magna-Plate 74 to American Foods Group ("American") in Green Bay, Wisconsin.
46. On March 8, 2007, the EPA conducted an investigation at American, located at 544 Acme Street, Green Bay, Wisconsin.
47. 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 3, 2006.
48. On March 16, 2007, the EPA inspector received two pieces of literature by mail from American that previously were given to American by Respondent.

49. 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 included Respondent's contact information such as a 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 included Respondent's contact information such as a 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."

50. 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 microbial 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 Respondent’s contact information such as phone number, facsimile number, and Internet address.

51. Respondent’s literature received by the EPA from American on March 16, 2007, claims, states or implies that JAX Halo-Guard FG-2 is a pesticide.

52. Respondent’s literature received by the EPA from American on March 16, 2007, claims, states or implies that JAX Magna-Plate 74 is a pesticide.

53. Respondent’s literature received by the EPA from American on March 16, 2007, claims, states or implies that JAX Magna-Plate 78 is a pesticide.

54. Respondent’s literature received by the EPA from American on March 16, 2007, claims, states or implies that JAX Poly-Guard FG-2 is a pesticide.

55. On March 29, 2007, the EPA inspector received another piece of literature from American, that previously was given to American by the Respondent.

56. 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 includes, 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.

C. Literature for Magna-Plate 78.

D. Literature entitled “Plant Microbial Knockdown Results” which includes references to JAX Poly-Guard FG-2.

E. Literature entitled “Major Food Processor Lab Test Results” which also makes references to JAX Poly-Guard FG-2.

F. Literature entitled “Independent Lab Results” which also makes references

to JAX Poly-Guard FG-2.

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.

57. Respondent's literature received by the EPA from American on March 29, 2007, claims, states or implies that JAX Halo-Guard FG-2 is a pesticide.
58. Respondent's literature received by the EPA from American on March 29, 2007, claims, states or implies that JAX Magna-Plate 78 is a pesticide.
59. Respondent's literature received by the EPA from American on March 29, 2007, claims, states or implies that JAX Poly-Guard FG-2 is a pesticide.
60. Respondent's literature found at American for JAX Magna-Plate 74 constitutes advertisements as defined in 40 C.F.R. § 168.22(a).
61. Respondent's literature found at American for JAX Magna-Plate 78 constitutes advertisements as defined in 40 C.F.R. § 168.22(a).
62. Respondent's literature found at American for JAX Poly-Guard FG-2 constitutes advertisements as defined in 40 C.F.R. § 168.22(a).
63. 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).
64. JAX Magna-Plate 78 is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).
65. On or about December 19, 2006, Respondent distributed or sold JAX Halo-Guard FG-2 to American in Green Bay, Wisconsin.
66. 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).

67. 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).
68. 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).
69. 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).
70. On or about December 19, 2006, Respondent distributed or sold JAX Magna-Plate 78 to American in Green Bay, Wisconsin.
71. 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).
72. On or about March 5, 2007, Respondent distributed or sold JAX Magna-Plate 78 to American in Green Bay, Wisconsin.
73. 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).
74. On or about March 3, 2006, Respondent distributed or sold JAX Magna-Plate 78 to American in Green Bay, Wisconsin.
75. Respondent distributed, offered for sale, or sold Magna-Plate 78 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).
76. On March 8, 2007, the EPA conducted an investigation at Badger, located at 3451 Johnson Avenue, Plover, Wisconsin.
77. During the investigation on March 8, 2007, the EPA inspector was taken to a supply area by Badger employees where he observed four boxes, each containing ten 14-ounce cartridge tubes of JAX Poly-Guard FG-2.
78. The inspector viewed a single tube from each of the four boxes in the storage room.

79. 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 the true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs."
80. 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.
81. During the visit on March 8, 2007, Badger also provided the inspector with a brochure that previously was given to Badger by Respondent.
82. The brochure was entitled "Food Grade Lubricants with Micronox™."
83. The brochure included a document entitled "What is JAX Micronox™ Technology? Re: Antimicrobial Usage in JAX Food-Grade Products" and described the antimicrobial capabilities of the Micronox technology found in Respondent's food grade lubricants.
84. 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.
85. The literature also included contact information for Respondent including Respondent's phone number, facsimile number, Internet, distributor information and product ordering options.
86. Respondent's literature found at Badger claims, states, or implies that JAX Poly-Guard FG-2 is a pesticide.
87. 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).
88. During the March 8, 2007 investigation, Badger gave the EPA 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 dates of June 15, 2006 and September 18, 2006.
89. On or about June 15, 2006, Respondent distributed or sold JAX Halo-Guard FG-2 to Badger in Plover, Wisconsin.
90. On or about September 18, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 to Badger in Plover, Wisconsin.

91. 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).
92. 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).
93. On March 7, 2007, the State of Minnesota Department of Agriculture conducted an inspection at Jennie-O Turkey Store (Jennie-O"), located 1530 30th Street SW, Wilmar, Minnesota.
94. During the March 7, 2007 inspection, the Minnesota inspector viewed and photographed a cartridge tube of JAX Halo-Guard FG-LT.
95. The labeling on the tube stated "JAX Halo-Guard FG-LT provides Micronox® microbial knockdown performance."
96. During the investigation, Jennie-O confirmed that the JAX Halo-Guard FG-LT was ordered on or about June 2006.
97. On or about June 27, 2006, Respondent distributed or sold JAX Halo-Guard FG-LT to Jennie-O in Wilmar, Minnesota.
98. Respondent distributed, offered for sale, or sold JAX Halo-Guard FG-LT on or about June 27, 2006 to Jennie-O, in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).
99. On March 7, 2007, the EPA conducted an investigation at Perlick, located at 8300 West Good Hope Road, Milwaukee, Wisconsin.
100. During the investigation on March 7, 2007, the inspector viewed a 14-ounce cartridge of Jax Poly-Guard FG-2.
101. 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."
102. 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 Behnke inspection.

103. On or about March 3, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 to Perlick.

104. Respondent distributed, offered for sale, or sold JAX Poly-Guard FG-2 to Perlick on or about March 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).

105. 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 Micronox®, 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."

106. 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.

107. 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).

108. 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.

109. 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).
110. 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.
111. Respondent's internet site on November 17, 2006 for JAX Halo-Guard FG-2 constitutes an advertisement as referenced in 40 C.F.R. § 168.22(a).
112. 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.
113. 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).
114. Behnke's products are required to be registered under FIFRA because they do not fall under the exemption defined in 40 C.F.R. § 152.5(d) which applies to products that are directly added to or placed onto the food to kill or mitigate microorganisms.
115. An appropriate and reasonable civil administrative penalty for Respondent's violations of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A), is \$55,055.

III. DISCUSSION

A. 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 under FIFRA, 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:

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 section 3. EPA interprets these provisions as

extending to advertisements in 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), define "pest" as "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 (as defined in FFDCA sec. 201(g)(1)) and cosmetics."

B. Burden of Proof

The Rules of Practice governing this administrative proceeding with respect to the burden of proof provide that the "complainant has the burdens of presentation and persuasion that the violation occurred as set forth in the complaint and that the relief sought is appropriate." 40 C.F.R. § 22.24(a). The EPA must prove its prima facie case by proving each jurisdictional element and the factual allegations supporting the violations charged. Under a preponderance of the evidence standard, the Complainant 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. *In the Matter of Standard Scrap Metal Co.*, 3 E.A.D. 267, *12 (EAB Aug. 2, 1990).

C. Elements of Proof

Complainant has alleged that, on eleven different occasions, Respondent distributed, offered for sale, or sold unregistered pesticides in violations of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A).¹

In its Answer, Behnke admits that it is a corporation organized under the laws of the State of Wisconsin. Answer ¶ 3. Respondent further admits that it is a "person" as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s). Answer ¶ 13. Respondent also admits that it distributed or sold its lubricants on the dates and to the customers alleged in each of the eleven counts of the

¹Complainant has proffered evidentiary material of additional sales in its Post-Hearing Brief. Specifically, Complainant has presented information that Respondent sold JAX Magna-Plate 74 to Sara-Lee on or about July 11, 2006 and JAX Halo-Guard FG-2 to Seneca on or about July 14, 2006. C's Ex. 11; C's Ex. 1; C's Post-Hearing Brief, pp. 22-23. However, I do not need to reach a decision on the alleged additional sales, and this decision is limited to allegations raised in the Complaint.

Complaint. It is undisputed that: (1) On August 3, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 by having the lubricant packed, labeled, and ready for shipment or sale. Answer ¶ 30, Joint Stip. ¶ 3; (2) On August 3, 2006, Respondent distributed or sold JAX Halo-Guard FG-2 by having the lubricant packed, labeled and ready for shipment or sale. Answer ¶ 54, Joint Stip. ¶ 3; (3) On December 19, 2006, Respondent distributed or sold JAX Halo-Guard FG-2 to American. Answer ¶ 101, Joint Stip. ¶ 30; (4) On December 19, 2006, Respondent distributed or sold JAX Magna-Plate 78 to American. Answer ¶ 102, Joint Stip. ¶ 31; (5) On March 5, 2007, Respondent distributed or sold JAX Magna-Plate 78 to American. Answer ¶ 103, Joint Stip. ¶ 32; (6) On March 3, 2006, Respondent distributed or sold JAX Magna-Plate 78 to American. Answer ¶ 104, Joint Stip. ¶ 33; (7) On March 3, 2006, Respondent distributed or sold JAX Magna-Plate 74 to American. Answer ¶ 105, Joint Stip. ¶ 21; (8) On September 18, 2006 Respondent distributed or sold JAX Poly-Guard FG-2 to Badger. Joint Stip. ¶ 45; (9) On June 15, 2006, Respondent distributed or sold Jax Poly-Guard FG-2 to Badger. Answer ¶ 124, Joint Stip. ¶ 10; (10) On June 27, 2006, Respondent distributed or sold JAX Halo-Guard FG-LT to Jennie-O. Answer ¶ 130, Joint Stip. ¶ 18; (11) On March 3, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 to Perlick. Answer ¶ 136, Joint Stip. ¶ 9. It is also undisputed that the products distributed or sold by Respondent were not registered as pesticides under FIFRA. Answer ¶¶ 27, 38, 50, 62, 75, 100, Joint Stip. ¶¶ 8, 14, 17, 20, 29.

The only remaining element of proof that Respondent has not admitted or stipulated to in its pleadings is whether JAX Poly-Guard FG-2, JAX Halo-Guard FG-2, JAX Magna-Plate 78, JAX Magna-Plate 74, JAX Poly-Guard FG-LT, and JAX Halo-Guard FG-LT ("Behnke's lubricants") are pesticides, as that term is defined under FIFRA and its implementing regulations.

D. Arguments

Behnke's lubricants are pesticides as defined by FIFRA

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.

a. Behnke's lubricants target "pests"

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). The term "pest" is qualified by 40 C.F.R. § 152.5(d) that provides 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..." Respondent asserts that the intended use of its lubricants fits within the "on or on processed food" exemption found at 40 C.F.R. § 152.5(d).²

My own review of the labels on the tubes of lubricant for the lubricants, the literature, and Respondent's website³ lead me to conclude that JAX Poly-Guard FG-2, JAX Halo-Guard FG-2, JAX Magna-Plate 78, JAX Magna-Plate 74, JAX Poly-Guard FG-LT, and JAX Halo-Guard FG-LT ("Behnke's lubricants") are pesticides as defined under FIFRA. One of the several pieces of Respondent's literature that was given to American and entered into evidence states, pertinent part:

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.

Joint Stipulated Facts ¶ 25 ("Joint Stip."); Complainant's Exhibit 8c ("C's Ex."). Also entered into evidence was a brochure given to Badger by Respondent which was entitled "Food Grade Lubricants with Micronox." The brochure described the antimicrobial capabilities of the Micronox technology found in Respondent's food grade lubricants and 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*. Joint Stip. ¶¶ 42-43; C's Ex. 8b.

The documentary evidence introduced at the hearing shows that Behnke's advertising and marketing claims consistently stated that its lubricants were intended to mitigate, destroy or control such microorganisms as *Listeria*, *E. coli* and *Salmonella*, which are bacteria known as pests. The regulations state 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..." 40 C.F.R. § 152.5(d). *Listeria*, *E.coli* and *Salmonella*, as bacteria, fit the definition of "pest" as set forth in the regulation (except where they are present "on or in living man or other living animals" or "on or in processed food").

One of the EPA's witnesses present at the hearing was Dr. Tajah Blackburn. Dr. Blackburn is employed by the EPA as an Efficacy Evaluation Team Leader in the Product Science Branch of the Antimicrobial Division of the Office of Pesticide Programs and holds a

²This argument will be addressed later in the decision.

³Although the EPA proffered documents from www.meatandpoultry.com as additional evidence, I need not reach a conclusion as whether Respondent has control of this site to the extent that Respondent made pesticidal claims. I do not reach a conclusion as to whether the EPA has established a sufficient nexus between this website and Respondent so as to sustain any charges of liability based on any pesticidal claims made in this linked site.

Ph.D. in Biomedical Sciences, with a concentration in Microbiology and Immunology. Transcript ("Tr.") April 1, pp. 449-459. Dr. Blackburn testified, among other things, that bacteria in general, but specifically *Listeria*, *E.coli* and *Salmonella*, are considered pests as defined by FIFRA. Tr. April 1, p. 432. Dr. Blackburn testified as to the dangers of *Listeria*, *E.coli* and *Salmonella*, explaining that these bacteria can cause gastroenteritis, gram-negative pneumonia, meningitis, septicemia, mastitis, and urinary tract infections and spontaneous abortions. In some cases, these diseases can lead to death. Tr. April 1, pp. 470-473. Dr. Blackburn's testimony demonstrates that these bacteria can be very dangerous to humans.

The EPA also called Mr. Dennis Edwards; Chief of the Regulatory Management Branch in the Antimicrobials Division of the Office of Pesticides Programs at the EPA. Mr. Edwards was established to have extensive knowledge and experience regarding the pesticide registration process. Over the course of his 30 year career, Mr. Edwards has implemented and applied FIFRA, its implementing regulations, and EPA's policies. Tr. April 1, pp. 234-265. Mr. Edwards testified that in his opinion, "based on the claims on the labels and the associated literature, the products should be registered as pesticide products." Tr. April 1, p. 235. Mr. Edwards also testified that *Listeria*, *E.coli* and *Salmonella* are considered pests as defined by FIFRA. Tr. April 1, p. 432.

I find both Mr. Edward's and Dr. Blackburn's testimony credible and unrebutted by Respondent. Additionally, the Environmental Appeals Board ("EAB") has previously found that *E.coli* and *Salmonella* are microorganisms infectious to man. See *In re Microban Products Company*, 11 E.A.D. 425 (EAB 2004); *In re Sultan Chemists, Inc.*, 9 E.A.D. 323 (EAB 2000), *aff'd Sultan Chemists, Inc. v. U.S. EPA*, 281 F.3d 73 (3rd Cir. 2002). It is my conclusion that *Listeria*, *E.coli*, and *Salmonella* are pests.

b. Behnke's intended use of the lubricants is that of a pesticide

FIFRA regulations make "intent" an element in determining whether a product is a pesticide requiring FIFRA registration. 40 C.F.R. § 152.15 states:

A pesticide is any substance (or mixture of substances) intended for pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a play 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 substances 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...

The EPA asserts that Behnke's labeling, advertising and marketing claims make implicit and explicit pesticidal claims. Complainant's Post-Hearing Brief, ("C's Post-Hearing Brief") p. 65.

Respondent provided American with literature that stated:

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.

C's Ex. 8b. I find that the use of the terms such as "kill" and "sanitization" in regard to bacteria clearly signal that Behnke intended their lubricants to be used for pesticidal purposes. After reviewing Behnke's labeling, advertising, and marketing claims, Mr. Edwards testified, "based on the claims being made, it's - these are pesticide claims, so the intent is that it be used as a pesticide product." Tr. April 1, p. 318.

Mr. Joshua Rybicki of the Inventory Control Division of American testified that his company bought JAX lubricants, including JAX Poly-Guard FG-2 with Micronox®, based on the antimicrobial claims made in literature supplied by Behnke. Mr. Rybicki stated that his company had been using another brand of lubricant that worked, but switched to JAX lubricants despite the 20% to 30% higher price because of the antimicrobial claims. Tr. March 31, pp. 88-90. Mr. Rybicki described some of the literature given to him by a Behnke salesperson (C's Ex. 8b), "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 - on any of the machinery that we use this on." Tr. March 31, p. 95. Although Respondent's cross-examination of Mr. Rybicki elicited testimony that he was not responsible for purchasing lubricants at American, such does not disturb Respondent's representations that are deemed to be pesticidal claims. Tr. March 31, p. 99.

The word "Micronox®" is a pesticidal claim

The EPA asserts that the trademarked name "Micronox" is itself a pesticide claim.⁴ Respondent uses this name throughout its labeling, making such statements as, "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" and "Micronox will supply immediate and significant knockdown capabilities." C's Ex. 8a; C's Ex. 8c.

⁴Although Respondent has not submitted any proof that Micronox has been trademarked, it has used the trademarked and registered trademarked term throughout its documents. Based on Respondent's representations, I will identify Micronox as a registered trademark product.

During the hearing, Mr. Edwards testified, "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." Tr. April 1, pp. 419-420. Mr. Edwards explained the term "knockdown" leads him to the opinion that the lubricant is a pesticide because, "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." Tr. April 1, p. 419-420.

The dictionary defines "knockdown" as "[f]orceful enough to knock down or overwhelm; Powerful. An act of knocking down. An overwhelming blow." Webster's II New Riverside University Dictionary (1994). Respondent's use of the word "nox" with its suggestion of the word "knockdown" in its advertising give the strong impression that the product is used for the purpose of preventing, destroying, repelling, or mitigating microorganisms. I find that the name "Micronox" clearly implies that the product is a pesticide.

Based on the foregoing discussion, I find that the EPA has established by a preponderance of the evidence that Behnke's lubricants are pesticides. The EPA has sustained its burden of showing that the lubricants are a pesticide subject to FIFRA. Respondent does not argue that Behnke's lubricants do not target bacteria. The question of whether an exemption from FIFRA applies is addressed next.

E. Defenses

In its Answer, at the hearing, and its Post-Hearing Brief, Respondent argues that it is exempt from FIFRA for a number of statutory and regulatory reasons.

Following complainant's establishment of a prima facie case, "respondent shall have the burden of presenting any defense to allegations set forth in the complaint and any response or evidence with respect to the appropriate relief. The respondent has the burdens of presentation and persuasion for any affirmative defense." 40 C.F.R. § 22.24(a). By seeking to invoke exemptions to the FIFRA regulations, Respondent is raising affirmative defenses and therefore bears the initial burden of production and the ultimate burden of persuasion for each affirmative defense. *In re Norman C. Mayes*, RCRA (9006) Appeal No. 04-01, 12 E.A.D. 54, slip op. at 48 n. 28 (EAB, March 3, 2005), *aff'd Norman C. Mayes v. Environmental Protection Agency*, 2008 U.S. Dist. LEXIS 700 (E.D. Tenn. January 4, 2008). See *In re New Waterbury, Ltd.*, TSCA Appeal No. 93-2, 5 E.A.D. 529, 540 n.20 (EAB, Oct. 20, 1994); *In re Standard Scrap Metal Co.*, 3 E.A.D. 267, 272 n.9 (EAB, Aug. 2, 1990); *U.S. v. First City National Bank of Houston*, 386 U.S. 361, 366 (1967) ("the party that claims the benefits of an exception to the prohibition of a statute carries the burden of proving that it falls within the exception."). Accordingly, Respondent must prove by a preponderance of the evidence each regulatory exemption raised.

In its Answer, Respondent lists seven interrelated "affirmative defenses." In particular, Respondent asserts the following: (1) Behnke's products are not "pesticides" within the meaning

of 7 U.S.C. § 136(u); (2) Behnke's products do not contain a "pesticide" as defined by 7 U.S.C. § 136(u); (3) Behnke's products are not "antimicrobial pesticides" within the meaning of 7 U.S.C. § 136(mm); (4) Behnke's products are not "pesticide chemicals" within the meaning of 21 U.S.C. § 321(q)(1)(A); (5) Behnke's products are "food additives" pursuant to 21 U.S.C. § 321(s) that are approved as lubricants with incidental food contact pursuant to 21 U.S.C. § 178.3570, a regulation promulgated pursuant to 21 U.S.C. § 348(a), and as such, Behnke's products are strictly regulated by the Food and Drug Administration ("FDA") pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act ("FFDCA"); (6) the intended use of Behnke's products is to protect components of equipment in food and beverage manufacturing plants from wear, corrosion, oxidation, and heat, so Behnke's products are formulated to protect themselves, by resisting internal degradation, from contaminants found in food processing environments; and (7) Behnke's products are not intended for a pesticidal purpose as set forth in 40 C.F.R. § 152.15, because a "pest" as defined in 40 C.F.R. § 152.5 does not include the microorganisms on or in processed food to which Behnke's products are exposed. Answer at 27-28.

Respondent did not directly pursue most of these defenses at the hearing or in its post-hearing brief, choosing to focus on the affirmative defense that its products target microorganisms on or in processed food, making it exempt from FIFRA regulation. Although Respondent's Post-Hearing Brief focuses on "on or in processed food", its other defenses are addressed nonetheless.⁵

Behnke's lubricants are "pesticides"

Respondent's first argument contends that it is that it is not subject to FIFRA because JAX Poly-Guard FG-2, JAX Halo-Guard FG-2, JAX Magna-Plate 78, JAX Magna-Plate 74, JAX Poly-Guard FG-LT, and JAX Halo-Guard FG-LT ("Behnke's lubricants") are not pesticides, as that term is defined under FIFRA and its implementing regulations. Answer p. 27. As discussed above, I find that Behnke's lubricants are pesticides and therefore subject to FIFRA.

Behnke's lubricants contain a "pesticide"

Respondent asserts that Behnke's lubricants do not contain a "pesticide" as defined by 7 U.S.C. § 136(u). Answer p. 27. As discussed above, Respondent's lubricants are pesticides. Therefore, they contain a pesticide. This argument has no merit.

Behnke's lubricants are not exempt as "antimicrobial pesticides" under Section 2(mm) of FIFRA

Respondent's third argument is that Behnke's products are not "antimicrobial pesticides" within the meaning of 7 U.S.C. § 136(mm) and are therefore exempt from FIFRA registration.

⁵Respondent's arguments were difficult to isolate and seemed to change in emphasis as the hearing progressed.

Ans. p. 27. Respondent renewed this argument in its Post-Hearing Brief after the evidentiary hearing. Respondent's Post-Hearing Brief, ("R's Post-Hearing Brief") pp. 8-9.

Complainant argues that Section 2(mm) does not exempt Behnke's lubricants from FIFRA registration. The definition of "antimicrobial pesticide" found in Section 2(mm) of FIFRA, 7 U.S.C. 136(mm), was added to FIFRA as part of the Food Quality Protection Act of 1996 ("FQPA"). In passing the FQPA, Congress added a special provision, now known as Section 3(h) of FIFRA, 7 U.S.C. § 136a(h), which was designed to establish deadlines for the registration of antimicrobial products that met the definition of "antimicrobial pesticide" set forth in Section 2(mm). The term "antimicrobial pesticide" does not appear in any other section of FIFRA except Section 2(mm) (where the term is defined) and Section 3(h) (which describes the registration process). Section 2(mm) does not limit the scope of FIFRA's regulatory coverage, nor does it affect the broad definition of "pesticide" set forth in Section 2(u) of FIFRA, 7 U.S.C. § 136(u). Section 2(mm) was established merely to create an expedited process for the EPA's review of FIFRA registration applications for certain antimicrobial products. C's Motion to Strike and Compel pp. 14-20 and 26-29. Mr. Edwards testified that "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." Tr. April 1 p. 336.

I find the EPA's argument persuasive. There is no merit to the argument that Section 2(mm) provides an exemption from FIFRA registration. The plain reading of the regulation and the legislative history clearly shows that Section 2(mm) only affects the time frame in which FIFRA registration of antimicrobial pesticides must be completed. Accordingly, I reject this defense.

Behnke's lubricants not exempt under 21 U.S.C. § 321(q)(1)(A)

Respondent's fourth affirmative defense makes the argument that Behnke's lubricants are not "pesticide chemicals" within the meaning of 21 U.S.C. § 321(q)(1)(A). Answer p. 27. This statutory provision is part of the Federal Food, Drug and Cosmetic Act ("FFDCA"). As pointed out by Complainant, the definition of "pesticide chemical" cited by Respondent was added to the FFDCA as part of the Antimicrobial Regulation Technical Corrections Act of 1998 ("ARTCA"), Pub.L. 105-324, §2(a). ARTCA only amended the FFDCA and did not amend any section of FIFRA. C's Motion to Strike and Compel, pp. 21-24.

The EPA asserts that whether or not Behnke's lubricants are "pesticide chemicals" under the FFDCA is irrelevant for this matter. Complainant asserts that the EPA's jurisdiction under the FFDCA is separate and distinct from the EPA's jurisdiction under FIFRA. Under the FFDCA, if a substance is a "pesticide chemical" then the EPA is authorized to modify or revoke a tolerance for residues of that substance in or around food. If the substance is deemed a "food additive" instead, then FFDCA regulatory coverage belongs to the FDA. However, the EPA has jurisdiction over any substance that is a "pesticide" as defined in Section 2(u) of FIFRA, 7 U.S.C. § 136j(u). The FDA has no part in the enforcement of FIFRA and FDA regulations have no

effect on whether a substance is a "pesticide" under FIFRA. Therefore, even if Behnke's lubricants are not "pesticide chemicals" within the meaning of 21 U.S.C. § 321(q)(1)(A), it has no bearing on whether the lubricants are "pesticides" under FIFRA. C's Motion to Strike, pp. 22-23. *See also* C's Ex. 19. In support of this contention, Complainant points to language in the ARTCA which provides, "[w]ith 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." 21 U.S.C. § 321(q)(1).

Respondent's argument has no merit. Whether a substance is a "pesticide chemical" under 21 U.S.C. § 321(s) of the FFDCA has no effect on whether the substance is a "pesticide" subject to the statutory coverage of FIFRA and its implementing regulations.

Behnke's products are "food additives" pursuant to 21 U.S.C. § 321(s) but are still regulated by the EPA

Respondent asserts that Behnke's products are "food additives" pursuant to 21 U.S.C. § 321(s) and are approved as lubricants with incidental food contact pursuant to 21 C.F.R. § 178.3570, a regulation promulgated pursuant to 21 U.S.C. § 348(a). Respondent states that it is anticipated that such products will be subject to incidental food contact and ingestion. Therefore, Respondent argues, its lubricants are strictly regulated by the FDA pursuant to the Section 409 of the FFDCA. Answer p. 28. Respondent also points out that its lubricants are sold only to the food and beverage processing industries. R's Post-Hearing Brief, p. 12.

The EPA contends that statutory citation of FFDCA cited by Respondent in support of its defense has no impact on the EPA's regulation of pesticides under FIFRA. C's Motion to Strike, p. 26. In support of this argument, the EPA points to a FDA guidance document introduced by Respondent which states:

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.

R's Ex. 53 at II, C. *See also* C's Post-Hearing Brief, p. 79.

The EPA makes a compelling argument. Respondent has not provided any probative evidence that shows that if a product is a "food additive" it is exempt from regulation as a pesticide under FIFRA. From my reading of the regulations, it is clear that a product could be regulated both by the EPA as a "pesticide" under FIFRA and by the FDA as a "food additive" under the FFDCA.

Expanding on this argument in its Post-Hearing Brief, Respondent also states that its products are not subject to FIFRA regulation because its lubricants fall within the regulatory