UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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| IN THE MATTER OF | ) | |
| 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 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. 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 fee, 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

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[1]Complainant 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 website[3] 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

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[2]This argument will be addressed later in the decision.

[3]Although 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, mastisis, 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.

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[4]Although 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.

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

Answ 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 irrevelent 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

definition of "food." 21 C.F.R. § 170.3(m) states that "[f]ood includes human food [and] substances migrating to food from food-contact articles." Based on this definition, Respondent asserts that "the Lubricants are indeed edible food articles and *are not*, therefore, subject to the same FIFRA registration as floor cleaners or wall sanitizers." R's Post-Hearing Brief, p. 11. In support of this argument, Respondent claims that testimony from witnesses provides evidence that Behnke's lubricants become part of processed foods. R's Post-Hearing Brief, p. 11.

While it is true that Behnke's lubricants may come in contact with processed food, in his testimony, Mr. Peter, the President of Behnke, stated that the lubricants are not designed to be applied onto or added into the processed food under the FDA. Tr. April 2, p. 718. This was further illustrated by the testimony of Mr. Rybicki, Inventory Control for American Foods Group, who testified that at the meat packing plant where he works, if the lubricant gets on the meat, "the meat is retained, shown to a USDA inspector. They will cut, like, the area or part of 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 onto production or if we have to condemn the carcass or piece of meat." Tr. March 31, p. 119. Carter Anderson, Respondent's witness and a Behnke salesman, testified, "[m]any types of lubricant come in contact with the food product. Everybody does everything they can to prevent that from happening." Tr. April 3, p. 874. It is clear from this testimony that the lubricants and greases used on the food processing plant machinery are not "food." I find that the Respondent's argument is without merit and that Behnke's lubricants are not "food" exempt from FIFRA regulation.

**Behnke's lubricants protect only themselves from environmental contaminants**

In its sixth defense, Respondent asserts that the intended use of Behnke's antimicrobial lubricants is simply "to protect components of equipment in food and beverage manufacturing plants from wear, corrosion, oxidation and heat. Behnke's products are formulated to resist internal degradation from contaminants found in food processing environments. As such, the products protect themselves, and only themselves, from such environmental contaminants." Answer p. 28. Respondent appears to be arguing that its lubricants are "treated articles or substances" as described in 40 C.F.R. § 152.25(a) and, therefore, are not required to be registered under FIFRA.

To qualify for the "treated articles or substances" exemption, the substance must meet the regulatory definition: "[a]n article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use." 40 C.F.R. § 152.25(a). As Complainant points out, this exemption only applies if Behnke's lubricants were treated with a pesticide that has been registered under FIFRA for use in protecting the lubricant. Respondent has failed to produce any evidence that the lubricants at issue contain or were treated with a pesticide registered with the EPA under FIFRA for use as an antimicrobial. C's Motion to Strike, pp. 29-30.

I find that Respondent's argument that its products fall within the "treated articles or substances" exemption has no merit.

**Behnke's lubricants are not exempt from FIFRA under the "on or in processed food" exemption**

Respondent's main argument is that its lubricants are not pesticides because they are not intended for preventing, destroying, repelling, or mitigating any "pest" within the meaning of FIFRA, because Behnke's lubricants target microbes "on or in processed foods" which are not "pests" within the meaning of FIFRA. Answer p. 28, R's Reply Brief, pp. 1-5. Mr. Peter testified that Behnke developed the antimicrobial lubricants in response to a problem faced by a large food company in its food processing facilities. Apparently, the company was concerned that the ball bearings in its equipment were transferring microbes to its processed food. Tr. April 2, pp. 585-592. Respondent argues that "Behnke never intended the Lubricants to target microbes in general, but only those of concern when the Lubricants became an incidental part of the processed foods or beverages." R's Reply Brief, p. 2.

Mr. Peter and Mr. Paquette, the technical director at Behnke, both testified that the lubricants are not intended to be applied directly to the food. Tr. April 2, p. 718; Tr. April 3, p. 806. Larry Cooper, Industrial Maintenance Mechanic at Quaker Oats, testified that they discarded food that had grease on it. Tr. April 3, p. 852. Certainly, none of the lubricants' labeling instructed users to apply the lubricant directly to food. Respondent argues that "although Behnke's Lubricants may not be specifically designed to become part of the processed food, the reality is that contact between the Lubricants and processed foods is an unavoidable and expected part of the lubricating process." R's Reply Brief, pp. 4-5.

Complainant argues that the plain language of 40 C.F.R. § 152.5(d) clearly states that the "on or in processed food" exemption only applies to products that are directly added to or placed onto the food to kill or mitigate microorganisms. C's Post-Hearing Brief p. 58.[6] Complainant states "for an antimicrobial product to be exempt from FIFRA regulation by virtue of its targeting only microogranisms that are 'on or in processed food,' the antimicrobial product has 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.'" C's Post-Hearing Brief, p. 59. Therefore, antimicrobial substances used in food contact items such as paper or paperboard are considered to be "pesticides" under FIFRA by the

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[6]The EPA cites to the *"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 the EPA for the definition of "processed food" used when applying this exclusion. EPA interprets "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." C's Ex. 19.

EPA. C's Ex. 19. Complainant points out that the evidence produced at the hearing demonstrates that none of Behnke's lubricants are intended to be applied directly to food. The EPA argues that if the lubricants are not intended to be applied directly to processed food, the lubricants are not exempt from FIFRA under the "on or in processed food" exemption. C's Post-Hearing Brief, p. 59; C's Ex. 19.

Based on his 32 years experience at the EPA, Mr. Edwards testified that, in his opinion, the exemption does not apply to Behnke's lubricants. He came to this opinion after reviewing Behnke's literature and noting that none of the directions require the lubricant to be applied directly to, in, or on processed food. Mr. Edwards noted that the lubricants are intended to lubricate machinery, and only become part of the processed food through incidental contact. Tr. April 1, p. 329.

To help clarify our understanding of the "on or in processed food" exemption in 40 C.F.R. § 152.5(d), Mr. Edwards gave an example of a product where the "on or in processed food" exemption does apply. He named a Proctor & Gamble product called Fit which was applied to lettuce, tomato, and other items in restaurants' salad bars. According to Mr. Edwards, this antimicrobial product was used to prevent spoilage and bacteria. He noted that it was applied directly to the food and not to the counter or any other surface.. Tr. April 1, pp. 322-324. From this example, it is clear that Behnke's lubricants do not fall within the "on or in processed food" exemption as they are not applied directly to processed food.

As the Complainant persuasively points out, this matter is analogous to that faced by the federal court in *Kenepp v. American Edwards Laboratories*, 859 F. Supp. 809 (E.D. PA 1994). C's Post-Hearing Brief, pp. 56-57. The court in *Kenepp* was faced with the question of whether an antimicrobial product that targeted the Human Immunodeficiency Virus Type 1 ("HIV") on hospital instruments was a pesticide under FIFRA. The court found that the antimicrobial products were indeed pesticides within the meaning of FIFRA. Although the targeted microorganisms originates from a human being, it does not mean that the microorganism is always considered "on or in living man." Thus, when HIV contaminates a hospital instrument the microogranism is no longer "on or in a living man" and a product intended to kill the microorganism on the instrument is a pesticide requiring FIFRA registration. *Kenepp v. American Edwards Laboratories*, 859 F. Supp. 809, 816, n. 4(E.D. PA 1994).

Similarly, if a microorganism such as E.coli originates from processed food, and contaminates the machinery or the lubricant on that machinery, it is no longer "on or in processed food" and an antimicrobial product (such as Behnke's lubricants) that targets that microorganism on the machinery and/or in the lubricant is considered a pesticide under FIFRA. C's Post-Hearing Brief, pp. 56-57. Clearly, the antimicrobial lubricants were intended to protect the lubricants themselves and the equipment they touched, therefore preventing cross-contamination within the food processing facility.

Respondent's "on or in processed food" argument fails on another ground as well.

Complainant has produced evidence that the microbes meant to be mitigated by Behnke's lubricants, E.coli, Listeria, and Salmonella, do not necessarily originate in processed food nor may they be found solely on processed food. Dr. Blackburn testified that E.coli, Listeria and Salmonella can enter food processing facilities on the workers themselves. Additionally, in a food processing facility such as a cattle slaughter house, the animals track in fecal matter, or are covered in fecal matter, which has bacteria in it. The equipment in these facilities may become contaminated through the aerosolization of the microbes via blood splatter or fecal splatter. Within other food processing facilities, vegetables can become contaminated with microbes through manure used to fertilize the plants, from untreated water, and from the workers who handle the vegetables. Tr. April 1, pp. 476-480. Thus, the record shows that microbes can enter food processing facilities in a variety of ways, and then cross contaminate. There are microbes that do not originate "on or in processed food" and can be found elsewhere in the food processing facility. Therefore, Behnke's lubricants are not exempt under 40 C.F.R. § 152.5(d).

I find Complainant's argument persuasive for the reasons stated above and that Respondent's argument is without merit. Behnke's lubricants do not fall under the "on or in processed foods" exemption. The evidence itself clearly reflects that the intended use of the lubricants was not limited to mitigating bacteria on or in processed food. It is clear that the antimicrobial properties of the lubricants are intended to function on the lubricant itself, and on the equipment in the food processing facilities. Further, I find that the language used in the labels and advertising by Behnke clearly makes pesticidal claims not exclusively limited to a "on or in processed food" exception.

**Behnke's lubricants are not exempt under a "reasonable consumer within the context of the market" argument**

Respondent also argued at the hearing and in its Post-Hearing Brief that Behnke only markets and sells its lubricants for use by the food and beverage processing industry. Respondent claims Behnke's customers are aware that lubricants used in their plants will inevitably come into contact with their food and that Behnke's customers are sophisticated enough to know that Behnke's antimicrobial claims apply only to controlling microbes in or on processed foods. Therefore, Respondent claims, the lubricants are not pesticides. R's Post-Hearing Brief pp. 10-14.

In support of this argument, Respondent cites to *In the Matter of Caltech Indus., Inc.*, Docket No. 5-FIFRA-97-006 (ALJ June 9, 1998), which involved the sale and distribution of an unregistered pesticide in violation of FIFRA. Respondent argues that the ALJ concluded that the "intended use" of the product (in this case, Hospital Cleaning Towels with Bleach) must be considered applying the "reasonable consumer" objective standard and that the "reasonable consumer" must be understood within the context of the market for the product, such as the health care industry in *Caltech*. Respondent claims that a reasonable consumer in the food and beverage processing industry is concerned with microbes contaminating processed food, of which the lubricants may become a part. R's Post-Hearing Brief pp. 15-16.

I find Respondent's reliance on *Caltech* as support for its "reasonable consumer" argument misguided. While the Respondent in *Caltech* made a similar "reasonable consumer within the context of the market" argument, the ALJ denied the Complainant's motion for accelerated decision without addressing the merits of the parties' arguments. The ALJ noted in his order that the arguments of the parties could only be properly evaluated after an evidentiary hearing. *Caltech* eventually settled without an evidentiary hearing and without a final ruling on the respondent's "reasonable consumer" argument. Therefore, *Caltech* is not controlling in this matter. *In the Matter of Caltech Indus., Inc.*, Docket No. 5-FIFRA-97-006 (ALJ June 9, 1998). Finally, while I respect my colleagues' opinions, I am not bound by their decisions.

The EPA argues that Respondent's contention that Behnke's lubricants are sold to sophisticated food and beverage processing costumers is irrelevant to a determination of whether Behnke's lubricants are "pesticides" under FIFRA. Complainant contends that there is no exemption for registration of pesticides under FIFRA based on the customer to which the pesticide is sold. C' Reply Brief, p. 2. Even assuming that there was an exemption for products sold to a certain market, Complainant argues that there is nothing that limits the sale and use of Benhke's lubricants to the food processing industry. The EPA points to testimony from Mr. Peter, in which he stated that the lubricants could be sold to costumers outside of the food and beverage processing industry. C's Post-Hearing Brief, pp. 85-87. Under questioning by EPA counsel, Mr. Peter admitted that he would sell the lubricants to whoever wanted to buy them. Tr. April 2, p. 645.

I find that even if Behnke's lubricants are sold exclusively to the food and beverage processing industry, FIFRA and its implementing regulations do not include a pesticide registration exemption for instances when a product is being sold exclusively to a particular industry. FIFRA requires registration of pesticides regardless of the identity of the buyers. Having sophisticated customers does not absolve Respondent from meeting the regulatory and statutory requirements.

## IV. PENALTY

### Penalty Criteria

The Consolidated Rules of Practice govern the assessment of civil administrative penalties in this proceeding. Section 22.27(b) of the Consolidated Rules of Practice provides in pertinent part:

> [i]f the Presiding Officer determines that a violation has occurred and the complaint seeks a civil penalty, the Presiding Officer shall determine the amount of the recommended civil penalty based upon the evidence in the record and in accordance with any civil penalty criteria in the Act. The Presiding Officer shall consider any civil penalty guidelines issued under the Act...If the Presiding Officer decides to assess a penalty different in amount from the penalty proposed by complainant, the Presiding Officer shall set forth in the

initial decision the specific reasons for the increase or decrease.

40 C.F.R. § 22.27(b). The Complainant bears the burdens of presentation and persuasion to show that the relief sought in this case is "appropriate." 40 C.F.R. § 22.24(a).

In regard to any relevant "civil penalty criteria in the Act," Section 14(a) of FIFRA, 7 U.S.C. § 136l, governs the assessment of civil penalties for violations of Sections 3(a) and 12(a) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j (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.[7] 31 U.S.C. § 3701; 40 C.F.R. § 19.4.

Section 14(a)(4) of FIFRA further provides in pertinent part that:

> In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to:
>
> [1] the size of the business of the person charged,
>
> [2] the effect on the person's ability to continue in business, and
>
> [3] the gravity of the violation.

7 U.S.C. § 136*l*(a)(4) (numeration added).

To assist enforcement officials in taking the above factors into consideration when assessing penalties under FIFRA specific to any given case, on July 2, 1990, the EPA's Office of Compliance Monitoring, Office of Pesticides and Toxic Substances issued an Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act ("the ERP"). C's Ex. 33. The ERP sets forth a "five stage process" for computing a penalty in consideration of the three statutory penalty criteria set forth in Section 14(a)(4) of FIFRA. C's Ex. 33 at 18. The ERP is a guidance document intended to provide a rational, consistent and equitable calculation methodology for applying the statutory factors to particular cases. Compl. p. 39. While the

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[7]Pursuant to section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, each federal agency is required to issue regulations adjusting for inflation the maximum civil monetary penalties that can be imposed pursuant to such agency's statutes. The purpose of these adjustments is to maintain the deterrent effect of federal civil penalties and to further the policy goals of the laws. U.S. EPA publishes inflation-adjusted maximum penalties pursuant to the Debt Collection Improvement Act under 40 C.F.R. part 19.

ERP is not binding on Administrative Law Judges, the EAB has emphasized that the Agency's penalty policies should be applied whenever possible. *In re Carroll Oil Co.*, RCRA (9006) Appeal No. 01-02, 10 E.A.D. 635, 656 (EAB, July 31, 2002). However, a penalty policy is not unquestioningly applied as if the policy were a rule with "binding effect." *Employers Insurance of Wausau and Group Eight Technology, Inc.*, TSCA Appeal No. 95-6, 6 E.A.D. 735, 755-762 (EAB, Feb. 11, 1997). The ALJ is required to consider the civil penalty guidelines but may give specific reasons for deviating from the amount of the penalty proposed by the Complainant. 40 C.F.R. § 22.27(b).

**Discussion of Penalty Criteria**

In the Complaint filed against Respondent and at the hearing, the EPA proposed a total civil penalty of $ 50,050 for the violations of FIFRA cited in Counts 1 through 11. Complainant argues that it properly applied the FIFRA statutory penalty factors and the ERP, it has met its burdens, and the imposition of a penalty of $50,050 is appropriate in this case. Mr. Robert Bonace, a Life Scientist with the EPA, testified that he calculated this penalty for the EPA utilizing the ERP. Tr. March 31, p. 186. Complainant also hired an outside consultant on financial analysis, Mr. Mark Ewen of Industrial Economics, to help calculate the proposed penalty. C's Post-Hearing Brief, p. 109. *See also* C's Ex. 32.

Respondent argues that the penalty proposed by the EPA is excessive and that the appropriate penalty is $0, or at most, $2,275 per violation. Resp's Post-Hearing Brief p. 17.

**Size of the Business**

The EPA first considered the appropriateness of the proposed penalty by examining publicly-available financial information on Behnke. Relying upon a Dun & Bradstreet report (C's Ex. 14b), which reflected that Respondent had annual gross sales in the amount of $7,900,000, Mr. Bonace determined that the penalty was appropriate for a business this size. Tr. March 31, p. 189; C's Post-Hearing Brief, p. 109. Respondent has explicitly waived any challenge to the proposed penalty based on the size of business. R's Post-Hearing Brief pp. 16-17.

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

The EPA stated that it considered the effect of the proposed penalty on Respondent's ability to continue in business. In doing so, Complainant hired an outside consultant in financial analysis, Mr. Mark Ewen of Industrial Economics. Mr. Ewen was hired to review several different items of publicly-available information regarding Behnke's financial condition. C's Post-Hearing Brief, p. 109; C's Ex. 32.

However, Respondent admitted in its prehearing exchange that it would be able to pay the total penalty proposed in the Complaint and specifically waived any objection to the proposed

penalty based on its inability to pay or the effect on Behnke's ability to continue in business. R's Resp. To Mots. To Strike and Compel at 24. Moreover, in Respondent's Post-Hearing Brief, Respondent again waived any challenge to the proposed penalty based on inability to pay. R's Post-Hearing Brief, pp. 16-17. *See also* Tr. March 31, p. 190. Respondent has also declined to provide any evidence concerning its financial condition, which would be necessary in order to support an inability to pay claim. *In re New Waterbury*, 5 E.A.D. 529, 541-542 (EAB 1994).

**Gravity of the Violation**

Complainant contends that the proposed penalty of $50,050 is appropriate in light of the "gravity" of the violations. Complainant argues that Respondent's violations of FIFRA present a potential danger to public health, and therefore involve substantial gravity. Complainant notes that Respondent's violations involve the distribution or sale of unregistered pesticides. Respondent claimed that these pesticides would be effective against harmful bacteria such as Listeria, E. coli, and Salmonella but failed to submit their products to the EPA's efficacy evaluation process. Complainant argues that Behnke introduced into commerce products that made antimicrobial claims, but that had never been proved to be effective under the strict EPA efficacy evaluations in controlling microorganisms to the extent that Behnke claimed in its labeling and advertisements. C's Post-Hearing Brief, pp. 110-111.

**Potential Harm to the Public**

Dr. Blackburn testified about the importance of EPA's efficacy evaluations in order to ensure that antimicrobial products are as effective as advertised. As discussed above, Behnke's lubricants at issue were labeled as targeting bacteria such as Listeria, E.coli, and Salmonella. Dr. Blackburn testified that advertising claims that mention such bacteria are "public health claims" and therefore very important to the EPA. Tr. April 1, p. 485. Dr. Blackburn stated that efficacy evaluations of antimicrobials are:

> critical because these organisms are public health organisms. We know that they directly impact man, are infectious to man, they're pathogenic towards man. And it's important that we have the confidence that these products will work against these pathogenic organisms before they're registered by evaluating the data that's generated.

Tr. April 1, p. 496.

Dr. Blackburn testified that she considered efficacy evaluations always important, but that they are especially important when the product is meant to be used in hospitals and food processing areas. *Id.* Dr. Blackburn explained:

> 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.

Tr. April 1, pp. 496-497. As Respondent has pointed out, their lubricants are directed towards the food processing industry, and have been used by several large companies, including Kraft and Quaker Oats. R's Reply Brief, pp. 2-3.

Mr. Edwards also testified to the importance of efficacy testing of antimicrobial products. He stated that if a product did not live up to its claims, "then at the very least you could end up with cross-contamination, with whatever the public health organism is, going from one site to the other. And then the worst, you could end up with somebody at some point getting sick." Tr. April 1, p. 250. Dr. Blackburn testified as to the serious illnesses associated with Listeria, E.coli, and Salmonella that could occur if food contaminated with the bacteria was consumed by humans. Salmonella causes gastroenteritis, which in some instances, can result in death for the elderly, infants, immunocompromised, and immunosuppressed individuals. Tr. April 1, p. 470-471. Dr. Blackburn explained that E.coli can also cause gastroenteritis, as well as gram-negative pneumonia, meningitis, septicemia, mastisis, and urinary tract infections. Septicemia can also cause death. Meningitis is the inflammation of the brain lining, and can also cause death. *Id.* at 472-473. Listeria also causes gastroenteritis, septicemia, meningitis, and spontaneous abortions. *Id.* at 474. Dr. Blackburn's testimony as to the deadly effect of these bacteria demonstrates the importance of regulatory oversight of antimicrobial products in order to evaluate the truth of their antimicrobial claims, thereby preventing exposure of the public to the risk of disease.

In support of a lower penalty, Respondent states that Behnke has always sold its antimicrobial lubricants in compliance with FDA requirements under the FFDRA, and argues that therefore, the potential harm to the public was nominal. R's Reply Brief, p. 12. Respondent's argument ignores the fact that the FDA and EPA have different goals and requirements. While Behnke's lubricants are food additives within the FDA's regulations, this does not mean the lubricants were tested under EPA efficacy evaluation standards for their effect on bacteria. In fact, Dr. Blackburn testified that the FDA's guidance document (R's Ex. 53) could not serve as a substitute for the EPA guidelines on efficacy evaluations. Tr. April 2, p. 538. Dr. Blackburn points out that the FDA's guidance document does not have a set performance standard or go into the level of detail regarding testing requirements that the EPA does. *Id.* While Behnke's lubricants may be safe as food additives under the FDA, they still ran the risk of not living up to their bacteria-killing claims and thus exposing the public to deadly bacteria.

Respondent contends that Behnke and other third parties (such as Kraft) tested the lubricants to determine the efficacy of the lubricants in targeting microbes. R's Reply Brief, p. 12; Tr. April 3, pp. 775-778. Dr. Blackburn reviewed the lab test results on JAX Poly-Guard

FG-2 published by Respondent in some of its promotional material (C's Ex. 8c). Dr. Blackburn testified that the information provided was insufficient to evaluate the efficacy of the antimicrobial properties of the lubricant. Tr. April 2, p. 515. Dr. Blackburn noted that:

> [T]he data is silent on what test was actually conducted to generate the data. It's silent on the conduct, the study conduct, were the necessary controls present, what the contact time was for the products to be in contact with the surface, exposure time, the actual test organisms...I don't know what yeast colonies, what mold colonies they're referring to, what test organisms were tested. And the test method against is not present on any of these documents. The study conduct is missing as well.

Tr. April 2, pp. 515-516. Because of the missing information, Dr. Blackburn did not consider the data reliable. Tr. April 2, p. 516.

Therefore, I find that Respondent's argument that the potential harm to the public was nominal unpersuasive. Complainant has carried its burden of persuasion that the proposed penalty is appropriate in light of the gravity of the violation and the potential harm to the public.

**The ERP**

Under the ERP, the penalty is determined in a five stage process in consideration of Section 14(a)(4) criteria. These five steps are:

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

2. Determination of the size of 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.

C's Ex. 33 at 18.

In order to determine of the final gravity of the violation under the ERP, a two part process is followed. First, the appropriate gravity "level" of the violation is determined. 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. C's Ex. 33 at 21.

**Base Gravity Level**

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. C's Ex. 33 at A-1. I find that Complainant has correctly assigned a Level 2 violation to each of the 11 illegal distributions alleged in the Compliant.

**Size of Business Category**

As discussed above under the statutory factor, Complainant obtained a Dun & Bradstreet Report, printed June 6, 2006, that indicated that Behnke Lubricants Inc. had a sales volume of over $7,900,000. C's Ex. 14b. Complainant correctly placed Respondent in "Business Category I" as a respondent who is alleged to have violated Section 14(a)(1) of FIFRA and whose gross revenues/sales exceed $1 million.[8] C's Ex. 33 at 20; C's Post-Hearing Brief, p. 123. As previously stated, Respondent does not challenge this aspect of the penalty calculation. R's Post-Hearing Brief pp. 16-17.

**Civil Penalty Matrix**

The EPA used the ERP's Civil Penalty Matrix to assign a base penalty relative to the gravity of the violation and the size of the business. Each cell of the Civil Penalty 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 ERP, the base penalty assigned to a violation with a Level 2 Base Gravity Level and Business Category I is $5,000 (the original statutory maximum). Finally, following 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," the EPA arrived at an adjusted base penalty of $6,500 per violation. C's Post-Hearing Brief, p. 124.

**Gravity Adjustment Criteria**

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[8]ERP Table 2 divides FIFRA Section 14(a)(1) violators (registrants, wholesalers, distributors) into three business size categories. Category I are businesses with over $1,000,000 in gross revenues in the prior calendar year, Category II applies to businesses with prior year gross revenues from $300,001 to $1,000,000, and Category III are businesses with gross revenues at or below $300,000. C's Ex 33 at 20; Tr. March 31, p. 189.

Next, the EPA applied the Gravity Adjustment Criteria to the base penalty of $6,500. The ERP lists gravity adjustment criteria 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 from Appendix B are added together (up to a maximum total value of 21) and based upon Table 3 in the ERP, the gravity based penalty is either assessed as is, raised, or lowered. If the sum of the adjustment factors is 7 or below, the penalty is reduced or possibly eliminated. If the sum of the adjustment factors is between 8 to 12, the base penalty is assessed, and if the sum of adjustments is 13 or higher, the penalty is increased. C's Ex. 33, Appendix B, Table 3.

The ERP provides two choices for toxicity, either "1" or "2". Pesticides rating a "1" are those in Toxicity Categories II through IV, pesticides assigned the signal word "warning" or "caution" and those with no known chronic health effects. Pesticides rating a "2" are Toxicity Category I pesticides, pesticides requiring the signal word "danger", restricted use pesticides, pesticides that are flammable or explosive, or that cause chronic health effects. C's Ex. 33, Appendix B. Complainant has assigned a "pesticide" toxicity value of "1", based on the labels and advertisements, as the products were thought to be "food grade" and not toxic in themselves. C's Post-Hearing Brief, p. 125.

The EPA has also assigned a value of "1" to "harm to human health." C's Post-Hearing Brief, p. 125. The value of "1" means that the product represents "minor potential or actual harm to human health, neither serious nor widespread." C's Ex. 33 at B-1. Complainant has assigned a value of "1" to "harm to the environment." C's Post-Hearing Brief, p. 125. The value of "1" means the violations' potential for harm to the environment was minor, neither widespread nor substantial. C's Ex. 33 at B-1. These assignments were made at the initial filing of the Complaint. Based on testimony at the hearing, especially Dr. Blackburn's testimony, the EPA believes it could justify a higher assessment, but has elected not to depart from its original calculation. C's Post-Hearing Brief, p. 125.

Gravity of Misconduct includes "compliance history" and "culpability." C's Ex. 33, Appendix B. The EPA has assigned "compliance history" a value of zero, based on the absence of any record of any prior FIFRA violations by Respondent. C's Post-Hearing Brief, p. 126. I find that a "compliance history" value of zero is appropriate in this matter.

The EPA assigned "culpability" a value of "2", based on unknown culpability of the Respondent. Complainant believes that testimony adduced at the hearing would support a higher "culpability" level, but chooses to keep its original penalty calculation. C's Post-Hearing Brief, p. 126. Complainant points to the testimony regarding Respondent's communications with the NSF, in which the NSF told Respondent to register their product with the EPA as evidence that the violation was knowing and willful. Tr. March 31, pp. 190-195. The EPA also cites Respondent's continued violations even after the filing of the Complaint. C's Post-Hearing Brief, p. 126..

Respondent argues that the level "2" culpability assigned to it is incorrect. Instead, Respondent states that it should receive a level "0" culpability level. R's Post-Hearing Brief, p. 17. A level "0" culpability level is appropriate when "the violation was neither knowing nor willful and did not result from negligence. Violator instituted steps to correct the violation immediately after discovery of the violation." C's Ex. 33, at B-2. Respondent asserts that it attempted to comply with the EPA and NSF recommendations to the best of its ability. Respondent also stated that "it was only when Behnke believed that NSF and EPA's requests went too far that Behnke objected by asserting its legal rights." R's Reply Brief at 13. In regard to the violations committed after the Complaint was filed, Respondent argues that it should not be penalized for what it describes as "defending it good-faith interpretation of the law." R's Reply Brief, p. 13.

At the hearing, Mr. Bonace testified that in order to earn a culpability value of "0", the Respondent "would have had to taken steps to correct the violation and not - and the violation could not have been knowing." Tr. March 31, p. 195. While I am not penalizing Respondent in any way for seeking to go to hearing in this matter, the record before me does not support the finding that Respondent took steps to correct the violation and that the violation was unknowing. Therefore, I find Respondent's argument for a "0" culpability level unpersuasive.

**Complainant's Calculation of the Total Penalty**

At the next step, the EPA added together the values it had assigned to the five adjustment factors of pesticide toxicity (1), human harm (1), environmental harm (1), compliance history (0), and culpability (2), and obtained a Total Gravity Adjustment Value total of "5" for each violation. Under Table 3 of the ERP, a Total Gravity Adjustment Value of "5" means a reduction of the matrix value by 30 %. C's Ex. 33, p. 22. As each violation was initially assigned a matrix value of $6,500, the adjusted penalty for each violation is $4,550. Multiplying $4,550 by 11, the number of distributions, Complainant calculated a total proposed penalty of $50,050. C's Post-Hearing Brief, p. 126; C's Ex. 14a.

**Ability to Continue in Business**

As discussed above, the EPA considered the effect of the proposed penalty on Behnke's ability to continue in business through its financial analysis expert, Mr. Ewen of Industrial Economics. Mr. Ewen came to the conclusion, based on the available financial information, that Respondent could pay the proposed penalty. C's Ex. 32. The EPA considered a Dun & Bradstreet Report and a Waukesha County Tax Bill for the Behnke facility. Based on this information, the EPA determined that no reduction in the proposed penalty was necessary in order for Respondent to continue in business. C's Post-Hearing Brief, pp. 126-127. Again, Respondent waived any challenge to the proposed penalty based on ability to continue in business. R's Post-Hearing Brief pp. 16-17. Accordingly, no facts, testimony, or exhibits were introduced at the hearing regarding Respondent's inability to pay the proposed penalty of $50,050 because Respondent has affirmed that he is so able to pay.

**Discussions and Conclusions as to Methodology and Penalty Assessment**

I find that Complainant has calculated the proposed penalty in accordance with the Enforcement Penalty Policy for FIFRA and has taken into consideration all necessary statutory factors. However, under 40 C.F.R. § 22.27(b) an Administrative Law Judge has discretion to assess a penalty different in amount from the penalty proposed by the complaint, setting forth in the initial decision the specific reasons for the increase or decrease based on the evidence in the record and in accordance with the penalty criteria set forth in the applicable Act. The final assessment of civil penalties is committed to the informed discretion of the court. *See Catskill Mountains Chapter of Trout Unlimited, Inc. v. City of New York*, 451 F.3d 77, 87 (2nd Cir. 2006); *United States v. Gurley*, 384 F.3d 316, 324 (6th Cir. 2004); *reh'g denied* 2005 U.S. App. LEXIS 425 (6th Cir. January 6, 2005) (en banc).

Upon considering all the evidence, I find sufficient compelling reasons to depart from the EPA's calculation of the penalty in this case under the ERP. I agree with the EPA that the evidence produced at hearing supports a culpability level of "4."[9] Although EPA has chosen to stay with a culpability level of "2" in this case, I find that a culpability value of "4" should be assigned. A culpability level of "4" is assigned when there is a "knowing or willful violation of the statute. Knowledge of the general hazardousness of the action." C's Ex. 33 at B-2. Although the EPA has chosen to stay with its original penalty calculation, I find that a culpability level of "4" is more appropriate in this case.

Complainant has produced evidence that Respondent was warned by the NSF as early as 2003 that it was making antimicrobial claims that would require its products to be registered under FIFRA. C's Ex. 37; Tr. March 31, p. 194. Mr. Peter, the president of Behnke, admitted at the hearing in regard to Behnke's labeling, that NSF "conveyed that they thought that this would be - possibly run amuck of some EPA pesticide concerns." Tr. April 2, p. 599. Mr. Peter also testified that "I was approached with a concern about the language on our labeling by NSF." Tr. April 2, p. 599. Mr. Peter and Mr. Paquette both did some research into EPA and FIFRA regulations themselves. Tr. April 2, p. 654. Respondent clearly was aware that it might be subject to EPA regulations and made a decision to go forward without so much as checking with the EPA for clarification. At the hearing, Mr. Bonace, an experienced enforcement specialist with EPA, testified that he did not have this information when he originally calculated the penalty, and based on it, he would propose that the culpability level be changed to a "4." Tr. March 31, p. 197.

Behnke made a conscious business decision that it would go forward with its sale of the lubricants without registering with the EPA. Mr. Peter admitted at the hearing that "we did not want to be listed under FIFRA" (Tr. April 2, p. 653) and that "[w]e wanted to stay out of that bailiwick." Tr. April 2, p. 669. Mr. Peter testified that he did not want the lubricants to require FIFRA registration because of:

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[9]The ERP provides culpability levels of 0, 2, and 4 only. C's Ex. 33 at B-2.

> [T]he extensive and extremely expensive processes to go through to get these types of approvals and the subsequent possible state approvals, the different things there were needed. So we took the tact that we would, at all costs, do our best job to avoid language that would implicate us in FIFRA labeling and try and stay within the language that was given to us in the FDA guidelines.

Tr. April 2, p. 622. Mr. Peter also testified that having EPA registration would cause Behnke to lose its competitive edge over its competitors in the marketplace. Tr. April 2, p. 672. Mr. Peter admitted that selling its lubricants without EPA registration was a business decision. Tr. April 2, p. 673. He stated that he was willing to take the risk that EPA would eventually contact him in regard to the lubricants. *Id.*

Although the NSF pointed out that pesticidal claims on their lubricants could concern the EPA in 2003, Mr. Peter testified he did not contact the EPA to inquire if the lubricants needed to be registered with the EPA as a pesticide. Tr. April 2, p. 665. Mr. Peter attended a trade group annual meeting at which the EPA's Mr. Edwards gave a presentation on EPA registration of treated materials. Mr. Peter testified that he spoke with Mr. Edwards after the presentation but did not ask him any questions regarding Behnke's lubricants being subject to FIFRA registration. Mr. Peter also did not try to schedule a meeting with Mr. Edwards to clarify his understanding of EPA regulations. Mr. Peter testified that this was another business decision. Tr. April 2, pp. 686-694. After Mr. Saatkamp inspected Respondent's facility, Respondent still made a conscious business decision not to contact the EPA. Tr. April 2, pp. 673-674. Respondent's longstanding indifference to the applicable FIFRA regulations, given its long experience as a business operating in federally regulated arenas aggravates his culpability.

Even after the EPA filed a Complaint against Respondent, it continued to sell or distribute its unregistered pesticide products. Mr. Bonace testified that on the very first day of the hearing he checked Respondent's website and found that Behnke was still making pesticidal claims. Tr. March 31, p. 195. Almost one year after Respondent became aware of the Complaint and was notified that it was allegedly violating the federal regulations Respondent was still making pesticidal claims on its website. It was only after the first day of the hearing that Mr. Peter made sure that those claims were taken off of Behnke's website. Tr. April 2, p. 631. Respondent is culpable for avoiding its regulatory responsibilities under FIFRA, a behavior that is unacceptable and conflicts with the goals and undermines the purposes of the FIFRA. Based on the record before me, I find that a culpability level of "4" is appropriate in this matter.

Adding together the values assigned to the five adjustment factors of pesticide toxicity (1), human harm (1), environmental harm (1), compliance history (0), and culpability (4), I obtain a Total Gravity Adjustment Value total of 7 for each violation. Under Table 3 of the ERP, a Total Gravity Adjustment Value of "7" means a reduction of the matrix value by 10 %. C's Ex. 33, p. 22. As each violation was initially assigned a matrix value of $6,500, the adjusted penalty for each violation is $5,850. Multiplying $5,850 by 11, the number of distributions, the total

penalty warranted is $64,350. Nonetheless, I am capping the increase to 10% of the total proposed penalty, resulting in an assessed penalty of $55,055.

Given the seriousness of these violations, I find a $55,055 penalty reasonable and appropriate. This figure is deemed appropriate in light of the three statutory factors set forth in FIFRA Section 14(a)(4) and the ERP as discussed in more detail above.

## ORDER

1. Respondent Behnke Lubricants, Inc. is assessed a civil administrative penalty in the amount of $ 55,055.

2. Payment of the full amount of this civil administrative penalty shall be made within thirty (30) days after this Initial Decision becomes a final order under 40 C.F.R. § 22.27(c), as provided below.[10] Payment shall be made by submitting a certified or cashier's check in the

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[10]Alternatively, Respondent may make payment of the penalty as follows:

**WIRE TRANSFERS:**

Wire transfers should be directed to the Federal Reserve Bank of New York

Federal Reserve Bank of New York
ABA = 021030004
Account = 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York NY 10045
Field Tag 4200 of the Fedwire message should read " D 68010727 Environmental Protection Agency "

**OVERNIGHT MAIL:**

U.S. Bank
1005 Convention Plaza
Mail Station SL-MO-C2GL
St. Louis, MO 63101

Contact: Natalie Pearson
314-418-4087

**ACH (also known as REX or remittance express)**

amount of $55,055, payable to "Treasurer, United States of America," and mailed to:

**U.S. Environmental Protection Agency**
**Fines and Penalties**
**Cincinnati Finance Center**
**P.O. Box 979077**
**St. Louis, MO 63197-9000**

3. A transmittal letter identifying the subject case title and EPA docket number (FIFRA 05-2007-0025), as well as Respondent's name and address, must accompany the check.

4. If Respondent fails to pay the penalty within the prescribed statutory period after entry of the Order, interest on the civil penalty may be assessed. 31 U.S.C. § 3717; 31 C.F.R. §§ 13.11, 901.9.

## APPEAL RIGHTS

This Order constitutes an Initial Decision as provided in Section 22.17(c) of the Rules of Practice, 40 C.F.R. 22.17(c). Pursuant to Sections 22.17(c) and 22.30 of the Rules of Practice, 40 C.F.R. §§ 22.27(c) and 22.30, this Initial Decision shall become the Final Order of the Agency

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Automated Clearinghouse (ACH) for receiving US currency

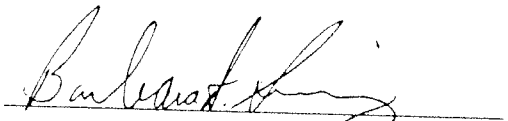
PNC Bank
808 17th Street, NW
Washington, DC 20074
Contact – Jesse White 301-887-6548
ABA = 051036706
Transaction Code 22 - checking
Environmental Protection Agency
Account 310006
CTX Format

**ON LINE PAYMENT:**

This payment option can be accessed from the information below:
WWW.PAY.GOV
Enter sfo 1.1 in the search field.
Open form and complete required fields.

unless an appeal is filed with the Environmental Appeals Board within thirty (30) days of service of this Order, or the Environmental Appeals Board elects, *sua sponte*, to review this decision.

Copies of this Order, the Initial Decision, dated December 30, 2008, are being served on both parties, as well as the Regional Hearing Clerk, in accordance with 40 C.F.R. § 22.27(a). However, this Initial Decision is not being released or made available to the public at this time, but will be publicly released on January 14, 2009, barring any persuasive objections. If either party objects to the Initial Decision on the basis of containing confidential business information ("CBI"), such objection must be served on the undersigned no later than January 12, 2009. The parties are reminded that the delayed public release of this Initial Decision does not affect the appeal period specified in 40 C.F.R. § 22.30.



Barbara A. Gunning
Administrative Law Judge

Dated: December 30, 2008
Washington, D.C.

In the Matter of *Behnke Lubricants, Inc.*, Respondent.
Docket No. FIFRA-05-2007-0025

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **INITIAL DECISION**, dated December 30, 2008, was sent this day in the following manner to the addressees listed below.

Mary Angeles
Legal Staff Assistant

Original and One Copy by Pouch Mail to:

Tywanna Greene
Acting Regional Hearing Clerk
U.S. EPA, Region V, MC-13J
77 West Jackson Blvd., 13th Floor
Chicago, IL 60604-3590

Copy by Certified Pouch Mail to:

Nidhi K. O'Meara, Esq.
James J. Cha, Esq.
Erik H. Olson, Esq.
Associate Regional Counsels
U.S. EPA, Region V, C-14J
77 West Jackson Boulevard
Chicago, IL 60604-3590



Copy by Certified Mail to:

Bruce A. McIlnay, Esq.
Linda S. Isnard, Esq.
Joseph F. Kirgues, Esq.
McIlnay & Button, Ltd.
1150 Washington Street
Grafton, WI 53024

**Dated: December 30, 2008**
**Washington, D.C.**

# ATTACHMENT A

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

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 May 7, 2007, the United States Environmental Protection Agency ("the EPA"), Region V ("Complainant" or "the Region"), 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. Complainant alleges that on at least eleven different instances, 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). Complainant proposes a civil administrative penalty of $50,050. Respondent filed its Answer and Request for Hearing ("Answer") on or about June 8, 2007. 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 (the "Rules of Practice"), 40 C.F.R. §§ 22.1-.32.

The undersigned entered a Prehearing Order on June 27, 2007, which, *inter alia*, set a schedule for the prehearing exchange. The parties have filed their prehearing exchange in this matter and reserved the right to supplement their prehearing exchange

and supplemental prehearing exchange.[1] The undersigned entered an Order Scheduling Hearing on January 14, 2008. The Hearing in this matter has been scheduled for Monday, March 31, 2008 commencing at 9:30 a.m. and to continue as found necessary through Friday, April 11, 2008, commencing at 8:30 a.m., excluding Wednesday, April 9, 2008, at the Waukesha County Courthouse in Waukesha County, Wisconsin. See 40 C.F.R. § 22.35(b).

## I. Complainant's Motion to Strike Affirmative Defenses and Complainant's Motion to Compel Discovery

### A. Procedural Background

On January 16, 2008, Complainant filed Complainant's Motion to Strike Affirmative Defenses ("Motion to Strike"), and Complainant's Motion to Compel Discovery ("Motion to Compel"). See 40 C.F.R. §§ 22.16(a) and 22.19(e).[2] Complainant's Motion to Strike requests that the undersigned strike four of the defenses Respondent lists as "affirmative defenses" on pages 27-28 of its Answer.[3] In particular, Respondent asserts the following as its "affirmative defenses": (1) Behnke's products are not "pesticides" within the meaning of 7 U.S.C. § 136(u); (2)

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[1] The parties are reminded that Sections 22.19(a) and 22.22(a) of the Rules of Practice provide that documents or exhibits that have not been exchanged and witnesses whose names have not been exchanged at least fifteen (15) days before the hearing date shall not be admitted into evidence or allowed to testify unless good cause is shown for failing to exchange the required information.

[2] Although Complainant has submitted these two motions within a single motion, the arguments for each are presented in distinct and separate sections of the motion. Thus, for ease of reference I assign each motion its own shorthand designation.

[3] In this motion, Complainant notes that it is unclear whether each of Respondent's asserted defenses in fact meet the standard for "affirmative defenses," yet nevertheless states, "For simplicity, Complainant will refer to these defenses as 'affirmative defenses' in the instant motion." See Mot. to Strike at n.1. I decline to take the same approach and will instead hereafter refer to Respondent's purported "affirmative defenses" as "defenses/affirmative defenses."

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 C.F.R. § 178.3570, a regulation promulgated pursuant to 21 U.S.C. § 348(a), which means 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.

Specifically, Complainant moves to strike Respondent's defenses/affirmative defenses 3, 4, 5, and 6 as legally insufficient defenses against liability. Mot. to Strike at 11. Thus, Complainant asserts that "[i]t is therefore unnecessary for this Court to engage in the time-consuming task of fact-finding in an evidentiary hearing on these defenses . . . [as they do not] have any legal affect on Respondent's liability for the violations of FIFRA alleged in the Complaint." *Id.* at 13.

With regard to Respondent's third defense/affirmative defense, Complainant argues that whether or not Behnke's products meet the definition of "antimicrobial pesticide" under FIFRA Section 2(mm) has no bearing on whether such products are "pesticides" within the meaning of FIFRA because "antimicrobial pesticides" are still subject to FIFRA registration; the potential designation of a product as an "antimicrobial pesticide" simply expedites review of the product's FIFRA registration application under FIFRA Section 3(h). *Id.* at 15-21. With regard to Respondent's fourth defense/affirmative defense, Complainant argues that whether or not Behnke's products are "pesticide chemicals" within the meaning of 21 U.S.C. § 321(q)(1)(A) has absolutely no bearing on whether the products are "pesticides" under FIFRA because the EPA's jurisdiction under the FFDCA is separate and distinct from the EPA's jurisdiction under FIFRA. *Id.* at 21-26. With regard to Respondent's fifth defense/affirmative defense, Complainant argues that, like the

"pesticide chemical" argument asserted in Respondent's fourth defense/affirmative defense, whether or not Behnke's products are "food additives" within the meaning of 21 U.S.C. § 321(s) that are regulated under the FFDCA does not affect whether the products are likewise "pesticides" regulated under FIFRA. Mot. to Strike at 26-29. Finally, with regard to Respondent's sixth defense/affirmative defense, Complainant interprets Respondent's language as implying that Behnke's products fall within the "Treated articles or substances" exemption set forth in FIFRA's implementing regulations at 40 C.F.R. § 152.25(a), and Complainant argues that even if this exemption applies, Behnke's Lubricants are still subject to FIFRA registration because the exemption requires that the article or substance at issue must contain, or have been treated with, a pesticide that has been registered under FIFRA for use in protecting the article or substance. *Id.* at 29-30.

Complainant's Motion to Compel seeks discovery in connection with Respondent's defenses/affirmative defenses 1, 2, and 7. Mot. to Compel at 30. Additionally, the Motion to Compel instructs that should the Motion to Strike be denied, Complainant moves in the alternative for discovery in connection with Respondent's defenses/affirmative defenses 5 and 6.[4] *Id.* Complainant argues that the undersigned should grant the discovery requests because the information sought is "required for Respondent to support its affirmative defenses." *Id.*

Specifically, Complainant requests eighteen categories of information, simplified in summary form as follows:

> (1) true, accurate and complete copies of all documentation or communication from and/or to any federal, state or local agency or authority relating to Behnke's lubricants, JAX Poly-Guard FG-2, JAX Halo-Guard FG-2, JAX Magna-Plate 78, JAX Magna Plate 74, JAX Halo-Guard FG-LT and JAX Poly-Guard FG-LT ("Behnke's Lubricants"), or concerning any lubricant containing Micronox;
> (2) a complete and accurate list of the chemical components of Behnke's Lubricants, by chemical name and by C.A.S. number;

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[4] Complainant is not seeking discovery of the information that it previously requested on June 21, 2007, in connection with Respondent's Affirmative Defenses 3 and 4. Mot. to Compel at n.8. Complainant maintains that information relating to these defenses cannot have any relevance to the issues presented in the instant case. *Id.*

(3) true, accurate and complete copies of all documents that specifically describe the intended uses of Behnke's products;
(4) a complete and detailed explanation, with substantiating documents, supporting Respondent's assertion that Behnke's products are strictly regulated by the Food & Drug Administration;
(5) true, accurate and complete copies of all documents containing evidence that any of Behnke's products at issue in this case were approved as lubricants with incidental food contact, including all notifications submitted to FDA or the Department of Health and Human Services ("DHHS") regarding Behnke's Lubricants;
(6) true, accurate and complete copies of all documents containing information about the identity and intended use of the lubricant/food contact substance, and Behnke's determination that such intended use was safe in accordance with Section 409(c)(3)(A) of the FFDCA;
(7) a complete and accurate statement explaining how Behnke's Lubricants can be safely used on machinery that is used for packing, manufacturing, processing, preparing, treating, packaging, transporting, or holding food;
(8) A statement specifying whether each of Behnke's Lubricants can be used safely because the lubricants are prepared from substances that are either generally recognized as safe for use in food, that are used in accordance with the provisions of a prior sanction or approval, or that are identified in 21 C.F.R. Section 178.3570(a)(3);
(9) a statement identifying the specific substance in each lubricant that fall in each category listed in the previous category of information requested, category 8;
(10) true, accurate and complete copies of all documentation and communications between Bennke and NSF International regarding any Behnke lubricants containing Micronox, and true, accurate and complete copies of all documents submitted by or on behalf of Behnke to NSF in connection with NSF's completion of its evaluation requirements for Behnke's Lubricants;
(11) a statement identifying how Behnke's Lubricants are formulated to resist internal degradation from contaminants found in food processing environments;
(12) a statement specifically identifying the contaminants that Behnke is referring to in its defense/affirmative defense number 6, and if such contaminants are microorganisms, an explanation as to how Behnke complied with the treated article exemption pursuant to 40 C.F.R. Section 152.25;

(13) a statement identifying the antimicrobial additive that is in each of Behnke's Lubricants, by chemical name, C.A.S. number, and EPA Registration number;
(14) a statement providing context for Respondent's prehearing exchange exhibit number 54 ("Behnke Publication regarding food grade lubricant certification");
(15) a statement as to whether Respondent intends to contest the amount of the proposed penalty, and if so, explaining in detail why and how Respondent believes the proposed penalty should be reduced or eliminated;
(16) true, accurate and complete copies of documents that show the actual gross sales or revenues of Behnke Lubricants, Inc., or a statement expressly waiving any objection to the penalty based on the "size of business" statutory penalty factor in Section 14(a)(4) of FIFRA, 7 U.S.C. § 136*l*(a)(4);
(17) a statement clarifying the relationship between Xact Fluid Solutions and Behnke; and
(18) revised narrative summaries of the expected testimony of Respondent's witnesses, inclusive of information and documents specifically requested in connection with each witness.

Mot. to Compel at 36-50. Complainant asserts that it makes the instant motion for this additional discovery in response to Respondent's failure to provide substantial evidence in support of its affirmative defenses in its prehearing exchange. *Id.* at 32-33.

On February 5, 2008, Respondent filed Respondent's Response to Complainant's Motion to Strike Respondent's Affirmative Defenses and Motion to Compel Discovery ("Response to Motions to Strike and Compel"). *See* 40 C.F.R. § 22.16(b). In support of its defenses/affirmative defenses, Respondent sets forth its contention that there are, among other disputed issues of fact, four primary issues of disputed fact in this matter: (1) whether its products are, in fact, "pesticides" within the meaning of FIFRA § 2u, 7 U.S.C. § 136(u), or are otherwise exempt from FIFRA regulation; (2) whether Behnke's Lubricants are "intended" for preventing, destroying, repelling, or mitigating any pest within the meaning of FIFRA § 2u; (3) whether Behnke's Lubricants "destroy, repel or mitigate" any "pest" within the meaning of FIFRA and its implementing regulations; and (4) whether Behnke's Lubricants are "food additives" subject to regulation under 21 U.S.C. § 348, *et seq.*, designated as such by the FDA. Resp. to Mots. to Strike and Compel at 3-7. In essence, Respondent argues that Behnke's Lubricants are intended to protect components of equipment in food and beverage manufacturing plants and are

formulated to have antimicrobial properties as to microorganisms generally found on or in processed foods and beverages. *Id.* at 9. As such, Respondent argues, the microbes to which Behnke's Lubricants are subjected are not "pests" and thus Respondent's claims regarding such microbes are not pesticidal claims. *Id.* at 9-10. Further, in its Response, Respondent argues that its seven defenses/affirmative defenses interrelate and, thus, should not be stricken separately. *Id.* at 8.

In response to Complainant's Motion to Compel, Respondent argues that it has complied with the disclosure requirements set forth in the undersigned's Orders and under the Rules of Practice, making the additional discovery sought by the Complainant unwarranted. Resp. to Mots. to Strike and Compel at 17. Moreover, Respondent suggests that Complainant's discovery requests are overly broad and unreasonably burdensome, and Respondent points out the timing issues that would arise should Complainant's Motion to Compel be granted.[5] *Id.* at 18-19, 21-22. Additionally, Respondent refutes Complainant's assertion that it is required to produce "substantial evidence" in the prehearing exchange to support its defenses, noting that much of the evidence it will use to support its defenses in this matter will be in the form of oral testimony. *Id.* at 20; *see* Mot. to Compel at 32-33. Respondent contends this proceeding is better served by EPA inquiring into specific matters of interest by cross-examination at the hearing, asserting, "Behnke understands that the introduction of documents at hearing not included in its prehearing exchange will not be allowed. EPA, therefore, has everything in its possession Behnke believes at the present time will support its case including exhibits and witness identities." Resp. to Mots. to Strike and Compel at 22-23.

Respondent admitted in its prehearing exchange that it would be able to pay the proposed penalty and specifically waived any objection to the civil penalties proposed in the Complaint based on its inability to pay or the effect on Behnke's ability to continue in business. *See* Resp. to Mots. to Strike and Compel at 24. In Respondent's Response to Motions to Strike and Compel, Respondent reiterates this and elaborates by asserting, "While not expressly stated [in the prehearing exchange], by implication, it is Behnke's intention to challenge the remaining factor in Complainant's calculation of a proposed penalty; namely, 'gravity of harm.'" *Id.* at 24.

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[5] The Motion to Compel was filed after the undersigned's January 14, 2008 Order setting the matter for hearing beginning March 31, 2009.

On February 11, 2008, Complainant filed Complainant's Reply to Respondent's Response to Complainant's Motion to Strike Respondent's Affirmative Defenses and Motion to Compel Discovery ("Reply to Response to Motions to Strike and Compel") and a Request for Order Requiring Respondent to Comply with Prehearing Order.[6] *See* 40 C.F.R. § 22.16(b). Concerning Respondent's Response to the Motion to Strike, Complainant reiterates its original arguments and avers that Respondent "largely fails to address the legal arguments advanced by Complainant, and the arguments advanced by Behnke are unsupported by the statutory language or legislative history of the laws cited by Respondent."[7] Reply to Resp. to Mots. to Strike and Compel at 3. Concerning Respondent's Response to the Motion to Compel, Complainant argues that Respondent has not been genuinely cooperative with respect to Complainant's stated need for additional documentary evidence, and that Complainant's Request for Voluntary Production of Information, filed on June 21, 2007 and renewed on November 15, 2007 in Complainant's Rebuttal Prehearing Exchange, gave Respondent and its legal counsel ample notice of the information Complainant would seek in discovery in this case should it not be provided voluntarily. *Id.* at 9-10. Complainant insists that Respondent's opposition to the Motion to Compel consists of "self-serving assertions . . . devoid of factual or legal support . . . [that] do not merit further response." *Id.* at 11. Additionally, Complainant takes particular issue with Respondent's narrative summaries of its witnesses' expected testimony, arguing they fail to provide basic factual information. *Id.* at 12-14. Finally, Complainant asserts that Respondent's arguments with respect to the proposed penalty in the Complaint are untimely and must be made in a supplemental prehearing exchange. *Id.* at 14-16.

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[6] Complainant's Request for Order Requiring Respondent to Comply with the Prehearing Order is received as a renewal of the requests Complainant made in its Motion to Compel and is thus incorporated into Complainant's Motion to Compel, which, as discussed, *infra*, is denied.

[7] Indeed, in Respondent's Response to Complainant's Motions to Strike and Compel, Respondent has not addressed the Region's extensive arguments concerning its position that the definition of "antimicrobial pesticide," under Section 2(mm) of FIFRA, exists only for purposes of Section 3(h) of FIFRA, a position which the Region supports with copious references to legislative history and guidance. *See* Reply to Resp. to Mots. to Strike and Compel at 3-4, citing Mot. to Strike at 14-20.

B. Standards for Adjudicating a Motion to Strike and a Motion to Compel Discovery

As a general principle, "administrative pleadings are liberally construed and easily amended." *In re Lazarus, Inc.*, TSCA Appeal No. 95-2, 7 E.A.D. 318, 334 (EAB 1997). The objective of pleading is to facilitate a decision based on the merits of a controversy. *Id.* at 333-34. Regarding motions to strike, such "are the appropriate remedy for the elimination of impertinent or redundant matter in any pleading, and are the primary procedure for objecting to an insufficient defense." *In re Dearborn Refining Co.*, Docket No. RCRA-05-2001-0019, 2003 EPA ALJ LEXIS 10, at *6 (EPA ALJ, Jan. 3, 2003). However, "motions to strike are generally viewed with disfavor because striking a portion of a pleading is a drastic remedy and because it is often sought by the movant simply as a dilatory tactic." *Id.* at 7 (internal quotation marks omitted).

In an administrative proceeding under 40 C.F.R. part 22, discovery does not take place automatically as a matter of right. Instead, most discovery, as it is typically thought of under the Federal Rules of Civil Procedure, occurs in an administrative proceeding through the prehearing information exchange. 40 C.F.R. § 22.19(a). The Rules of Practice do, however, provide that after the occurrence of the prehearing exchange provided for in 40 C.F.R. § 22.19(a), a party may seek additional discovery by way of written motion. 40 C.F.R. § 22.19(e). Section 22.19(e) of the Rules of Practice specifies that such "other discovery" may be ordered if it:

> (i) Will neither unreasonably delay the proceeding nor unreasonably burden the non-moving party;
> (ii) Seeks information that is most reasonably obtained from the non-moving party, and which the non-moving party has refused to provide voluntarily; *and*
> (iii) Seeks information that has *significant* probative value on a disputed issue of material fact relevant to liability or the relief sought.

*Id.* (emphasis added).

C. Discussion

As discussed, *supra*, Complainant moves to strike Respondent's defenses/affirmative defenses 3, 4, 5, and 6 as legally insufficient defenses against liability, arguing that engaging in time-consuming fact-finding in an evidentiary hearing on these defenses is therefore unnecessary. Mot. to Strike at 11-13. I note that in deciding on a motion to strike, all adverse inferences must be drawn in favor of the non-moving party. Without determining the validity or invalidity of Respondent's defenses/affirmative defenses at this time, it is possible that these defenses/affirmative defenses and the facts they place into genuine dispute may inform other aspects of the decision, namely the appropriateness of the proposed penalty,[8] and thus these defenses/affirmative defenses must be viewed in their entirety. Moreover, as pointed out by Respondent and acknowledged by Complainant, motions to strike are drastic and harsh remedies that are rarely used and typically viewed with disfavor by courts. Resp. to Mots. to Strike and Compel at 11-12; Mot. to Strike at 11-12. As such, I find it more appropriate to rule on the validity of Respondent's defenses/affirmative defenses within the context of an evidentiary hearing. Therefore, Complainant's Motion to Strike is **DENIED**.

Complainant's Motion to Compel is extensive. The Rules of Practice provide that I may only order such additional discovery if, *inter alia*, the information sought has "significant probative value" on a disputed issue of material fact. 40 C.F.R. § 22.19(e). It is questionable whether information potentially supporting the majority of Respondent's arguments, including its witness narratives, has significant probative value or relevance to the allegations in the Complaint. Thus, although I am not granting Complainant's Motion to Compel a revision/extension of Respondent's witness narratives, this instant ruling does not reflect on the merit of the narratives nor does it preclude EPA from objecting to the witness testimony at the hearing. A finding of the testimony's relevance and materiality may be more appropriately made at that time.

However, I find that Complainant has shown additional discovery is warranted under the standards of 40 C.F.R. § 22.19(e) with regard to two categories of information, namely Complainant's requests to obtain: (1) a complete and accurate

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[8] As pointed out by Complainant, Respondent's arguments with respect to the proposed penalty should not be made by implication; they should be made in a supplemental prehearing exchange. *See* Reply to Resp. to Mots. to Strike and Compel at 14; *See also* Resp. to Mots. to Strike and Compel at 24.

list of the chemical components of Behnke's Lubricants, by chemical name and by C.A.S. number;[9] and (2) true, accurate and complete copies of all documents that specifically describe the intended uses of Behnke's products. For purposes of this Order, these categories of information have been described, *supra*, as requests numbers 2 and 3 in the Motion to Compel. Thus, with respect to these two requests, Complainant's Motion to Compel is **GRANTED, IN PART.**

Before discussing my ruling on the remaining categories of information that Complainant seeks in its Motion to Compel, I remark on Complainant's discovery request for documents that show Behnke's actual gross sales or a statement from Respondent expressly waiving any objection to the penalty based on the "size of business" statutory penalty factor, which is summarized above as categorical request number 16 (*supra* p. 6). *See* Mot. to Compel at 47. As noted, *supra*, Respondent admitted in its prehearing exchange that it would be able to pay the total penalty proposed in the Complaint and specifically waived any objection to the proposed penalty based on its inability to pay or the effect on Behnke's ability to continue in business. *See* Resp. to Mots. to Strike and Compel at 24. Also, as noted, *supra*, in Respondent's Response to Motions to Strike and Compel, Respondent indicated that it intends to challenge the proposed penalty only on the basis of a single statutory penalty factor: the gravity of harm. *See Id.* and 7 U.S.C. § 136*l*(4). That is, Respondent has not indicated that it is challenging the Region's characterization of its "size of business." *See* 7 U.S.C. § 136*l*(4).

I note that the Region has not shown that it is unable to otherwise obtain documents or other information pertaining to Respondent's size of business. I observe that the Region need only show that it considered the "size of the business" statutory penalty factor, and it need not prove this factor unequivocally. *Cf. In re New Waterbury, Ltd.*, TSCA Appeal No. 93-2, 5 E.A.D. 529, 541 (EAB 1994) (Complainant has the burdens of production and persuasion to show that it considered the Respondent's ability to pay). Thus, as generally discussed immediately *infra*, Complainant's request to compel Respondent's production of

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[9] Should Respondent wish to have this information protected as trade secrets or confidential business information, Respondent need only identify this information as such and appropriate safeguards against unauthorized disclosure will be implemented in accordance with Section 10 of FIFRA, 7 U.S.C. § 136h, and 40 C.F.R. part 2.

information relating to the size of its business is not warranted.

With regard to all remaining categories of information that Complainant seeks in its Motion to Compel,[10] the Motion is **DENIED, IN PART.** In view of the parties' contrasting arguments, it has not been shown that this discovery will neither unreasonably delay the proceeding nor unreasonably burden the non-moving party, that this information is most reasonably obtained from the non-moving party, nor that this information has *significant* probative value on a disputed issue of material fact. Moreover, at present, I do not perceive much of this remaining information to be relevant, material, or of much probative value in the resolution of the instant matter. 40 C.F.R. § 22.22(a).

Furthermore, at this late stage in the proceeding, ordering Respondent to respond to Complainant's voluminous discovery requests appears unreasonably burdensome and prejudicial. As correctly noted by Complainant, Respondent has the burden of proving its defenses/affirmative defenses, and if the information necessary to prove such is not in Respondent's prehearing exchange, Respondent cannot rely on such information at the hearing. Respondent has in fact explicitly recognized that it is confined in the hearing to using only documents and witness testimony that it has previously disclosed in its prehearing information exchange and supplements thereto, so Respondent's failure to comply with the Complainant's prior information requests and current discovery requests will not prejudice Complainant.

## II. Complainant's Motion for Accelerated Decision on Liability and on Affirmative Defenses

### A. Procedural Background

On January 22, 2008, Complainant filed Complainant's Motion for Accelerated Decision on Liability and on Affirmative Defenses ("Motion for Accelerated Decision") concerning all eleven counts in the Complaint. *See* 40 C.F.R. § 22.20.[11] Complainant

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[10] Described, *supra*, as requests numbers 1 and 4-18 in the Motion to Compel.

[11] Several declarations in support thereof are attached to this Motion.

expresses its position that even in a light most favorable to Respondent, there is no genuine issue of material fact as to any of the elements necessary to prove that a violation of FIFRA occurred as to each of the eleven counts. Mot. for Acc. Dec. at 3. Moreover, Complainant moves for accelerated decision as to Respondent's defenses/affirmative defenses 1, 2, and 7, arguing that Respondent has simply stated legal conclusions and failed to support these defenses/affirmative defenses with any facts or reasoning which show that there is a genuine issue for hearing. *Id.* at 4, 47. Complainant also requests that its arguments against Respondent's defenses/affirmative defenses 3, 4, 5, and 6 set forth in the Motion to Strike be incorporated by reference should the undersigned find it more appropriate to address these defenses/affirmative defenses in the context of accelerated decision. *Id.* at 4-5.

Complainant asserts that the record in this matter, together with any declarations, demonstrates that there are no genuine issues of material fact concerning the following with respect to each of the eleven counts alleged in the Complaint: that Respondent is a "person," as defined by Section 2(s) of FIFRA, in "any state," who distributed or sold a product, as defined by Section 2(gg) of FIFRA, that was a "pesticide," as defined by Section 2(u) of FIFRA, yet was not registered as a pesticide under Section 3 of FIFRA. Mot. for Acc. Dec. at 9-46. Thus, Complainant argues that it is entitled to judgment as a matter of law and accelerated decision on all eleven separate counts as alleged in the Complaint. *Id.* at 9.

Concerning Respondent's defenses/affirmative defenses, Complainant argues that "Respondent must provide substantial evidence in support of its affirmative defenses" as part of its prehearing exchange. Complainant asserts that "Respondent has provided very little information to support its {defenses/} affirmative defenses 1 and 7, and it seems these two defenses are closely interrelated," as Respondent asserts its products are not "pesticides" within the meaning of FIFRA in defense/affirmative defense 1 and then asserts in defense/affirmative defense 2 that its products are not intended for a pesticidal purpose because they do not target a "pest" as defined by 40 C.F.R. § 152.5. Mot. for Acc. Dec. at 50. Complainant then explains its interpretations of what "Respondent seems to be asserting" and the arguments that "Behnke could be making." *Id.* at 50-54.

With regard to Respondent's defense/affirmative defense 2, Complainant insists that Respondent's position that "Behnke's products do not contain a 'pesticide' as defined by FIFRA . . . misses the point entirely . . . {because while} products that

contain pesticides might require registration under FIFRA before these products can be distributed or sold, it is not the single means by which such products might require registration under FIFRA." Mot. for Acc. Dec. at 54. Complainant argues that the word "intended" in the definition of "pesticide" in FIFRA is critical, and Respondent "clearly claimed, stated and implied by its labeling and advertising . . . that its lubricants had antimicrobial properties and could or should be used as a pesticide." *Id.* at 54-55.

On January 28, 2008, Respondent submitted Respondent's Motion Requesting an Extension of Time to File Opposition to Complainant's Motion for Accelerated Decision ("Request for Extension of Time"), in which Respondent requested an extension of time not to exceed fifteen (15) days to file a response to the Motion for Accelerated Decision. Given the length and breadth of Complainant's pending above-described motions, on January 29, 2008, the undersigned found good cause and orally granted Respondent's Request for Extension of Time, extending the due date for Respondent's response to the Motion for Accelerated Decision to February 21, 2008. 40 C.F.R. § 22.7(b). On February 21, 2008, Respondent filed Respondent's Response to Complainant's Motion for Accelerated Decision on Liability and on Affirmative Defenses ("Response to Motion for Accelerated Decision").

In its Response, Respondent contends that it is inappropriate to decide the merits of the instant matter on a motion for accelerated decision due to the existence of genuine issues of material fact. Resp. to Mot. for Acc. Dec. at 1. Respondent presents its opposition to Complainant's interpretation of the facts in the instant matter by summarizing what Respondent believes are the three main issues in controversy: (1) Whether Behnke's Lubricants relate to "pests," as defined in 40 C.F.R. § 152.3, if Behnke's Lubricants are anticipated as becoming part of processed food and deemed as "food additives" safe for human consumption pursuant to Section 409 of the FFDCA; (2) whether Behnke's Lubricants fall within the definition of "pesticides" requiring registration under FIFRA within the meaning of 40 C.F.R. § 152.3; and (3) whether "reasonable consumers" within the food and beverage processing industries would interpret Behnke's statements regarding the antimicrobial properties of the Lubricants as suggesting that the Lubricants "can or should" be used as pesticides within the meaning of 40 C.F.R. § 152.15(a)(1), so as to construe Behnke's statements as "pesticidal claims." *Id.* at 1-2, 19. Thus, Respondent argues there are genuine issues of material fact regarding the incorporation of Behnke's Lubricants into processed foods when used for their intended purpose, regarding the market

for, and intended use of, Behnke's Lubricants, and regarding the sophistication and understanding of the consumers within the relevant market for Behnke's Lubricants. *Id.* at 1-2, 20-32.

Respondent further argues that its defenses/affirmative defenses 1, 2, and 7 are interrelated and collectively raise the issue of whether Behnke's Lubricants are pesticides within the meaning of FIFRA, interweaving these defenses/affirmative defenses into Respondent's defense in this matter as a whole. Therefore, Respondent asserts, if accelerated decision on liability is denied in this matter, then an accelerated decision on the affirmative defenses must be similarly denied. Resp. to Mot. for Acc. Dec. at 20. Respondent also takes issue with Complainant's claim that it must provide "substantial evidence" in support of its affirmative defenses at the accelerated decision stage, arguing instead that a party responding to a motion for accelerated decision need only produce "some evidence" to place the moving party's evidence in question and raise a question of fact for an adjudicatory hearing. *Id.* at 21(citations omitted).

On February 27, 2008, Complainant filed Complainant's Reply to Respondent's Response to Complainant's Motion for Accelerated Decision on Liability and on Affirmative Defenses("Reply to Response to Motion for Accelerated Decision").[12] *See* 40 C.F.R. § 22.16(b). In this Reply, Complainant reiterates its previous arguments concerning accelerated decision in this matter and reveals that the focal point of dispute concerns the parties' contentions regarding the processed food exemption.[13]

Specifically, Complainant makes three main arguments in its Reply to Respondent's Response to Motion for Accelerated Decision. First, Complainant argues that Respondent fails to recognize that the controlling statute in this case is FIFRA, not

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[12] The undersigned's office received a facsimile copy on March 3, 2008.

[13] In addition setting forth arguments in its Reply, Complainant also raises the objection that "Behnke refers to numerous additional witnesses and documentation [in Respondent's Response to Motion for Accelerated Decision] that it had not submitted in its Prehearing Exchange." Reply to Resp. to Mot. for Acc. Dec. at 16. Despite its demonstrated proficiency with the record in this matter, Complainant fails to specify the purported additional witnesses and documentation to which it refers. *Id.* *See, e.g.*, *Id.* at 6-7.

the FFDCA. Reply to Resp. to Mot. for Acc. Dec. at 1-5. In this regard, Complainant asserts that all discussions concerning the FFDCA are "red herrings" because FFDCA and FDA Guidance state that the FFDCA does not affect FIFRA jurisdiction and because whether Behnke's Lubricants are "food additives" under the FFDCA is of no consequence to whether Behnke's Lubricants are "pesticides" under Section 2(u) of FIFRA, 7 U.S.C. § 136(u). *Id.* Second, Complainant argues that Respondent does not become exempt from FIFRA by shifting its position on the "intended use" of Behnke's Lubricants, a question that is critical in determining Respondent's liability in this matter. *Id.* at 5-12. In particular, Complainant asserts that Respondent cannot escape the implicit and explicit claims it has made in advertising Micronox antimicrobial technology in Behnke's Lubricants, that Complainant does not consider Behnke's Lubricants to be "processed foods," and that Complainant does not consider Behnke's Lubricants as intended to treat "processed foods." *Id.* Finally, Complainant argues that Respondent's contentions concerning the sophistication of Behnke's buyers are irrelevant because FIFRA and its implementing regulations do not include a pesticide registration exemption for instances when a product is being sold exclusively to a particular industry. *Id.*. at 12-16. Complainant elaborates by noting that FIFRA requires registration of pesticides regardless of the identity of the buyer and that FIFRA jurisdiction is not dictated by how pesticide registration may affect a registrant's sale of its products. *Id.*

## B. Standard for Adjudicating a Motion for Accelerated Decision

Section 22.20(a) of the Consolidated Rules of Practice authorizes the Administrative Law Judge to "render an accelerated decision in favor of a party as to any or all parts of the proceeding, without further hearing or upon such limited additional evidence, such as affidavits, as he may require, if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law." 40 C.F.R. § 22.20(a).

Motions for accelerated decision under 40 C.F.R. § 22.20(a) are akin to motions for summary judgment under Rule 56 of the Federal Rules of Civil Procedure ("FRCP"). *See, e.g., BWX Technologies, Inc.*, 9 E.A.D. 61, 74-75 (EAB 2000); *In the Matter of Belmont Plating Works*, Docket No. RCRA-5-2001-0013, 2002 EPA ALJ LEXIS 65 at *8 (ALJ, Sept. 11, 2002). Rule 56(c) of the FRCP provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of any material fact and that the moving party is entitled to a judgment as a matter of law."

Therefore, federal court decisions interpreting Rule 56 provide guidance for adjudicating motions for accelerated decision. *See CWM Chemical Service*, 6 E.A.D. 1 (EAB 1995).

The United States Supreme Court has held that the burden of showing that no genuine issue of material fact exists is on the party moving for summary judgment. *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 157 (1970). In considering such a motion, the Tribunal must construe the evidentiary material and reasonable inferences drawn therefrom in the light most favorable to the non-moving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1985); *Adickes*, 398 U.S. at 158-59; *see also Cone v. Longmont United Hospital Assoc.*, 14 F.3d 526, 528 (10th Cir. 1994). Summary judgment on a matter is inappropriate when contradictory inferences may be drawn from the evidence. *Rogers Corp. v. EPA*, 275 F.3d 1096, 1103 (D.C. Cir. 2002).

In assessing materiality for summary judgment purposes, the Supreme Court has determined that a factual dispute is material where, under the governing law, it might affect the outcome of the proceeding. *Anderson*, 477 U.S. at 248; *Adickes*, 398 U.S. at 158-159. The substantive law involved in the proceeding identifies which facts are material. *Id.*

The Supreme Court has found that a factual dispute is genuine if the evidence is such that a reasonable finder of fact could return a verdict in favor of the non-moving party. *Id.* In determining whether a genuine issue of fact exists, the judge must decide whether a finder of fact could reasonably find for the non-moving party under the evidentiary standards in a particular proceeding. *Anderson*, 477 U.S. at 252.

Once the party moving for summary judgment meets its burden of showing the absence of genuine issues of material fact, Rule 56(e) requires the opposing party to offer countering evidentiary material or to file a Rule 56(f) affidavit. Under Rule 56(e), "When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial." The Supreme Court has found that the non-moving party must present "affirmative evidence" and that it cannot defeat the motion without offering "any significant probative evidence tending to support" its pleadings. *Anderson*, 477 U.S. at 256 (quoting *First Nat'l Bank of Arizona v. Cities Service Co.*, 391 U.S. 253, 290 (1968)).

More specifically, the Court has ruled that the mere allegation of a factual dispute will not defeat a properly supported motion for summary judgment, as Rule 56(e) requires the opposing party to go beyond the pleadings. *Celotex Corp. v. Catrett*, 477 U.S. 317 at 322 (1986); *Adickes*, 398 U.S. at 160. Similarly, a simple denial of liability is inadequate to demonstrate that an issue of fact does indeed exist in a matter. *In the Matter of Strong Steel Products*, Docket Nos. RCRA-05-2001-0016, CAA-05-2001-0020, and MM-05-2001-0006, 2002 EPA ALJ LEXIS 57 at *22 (ALJ, September 9, 2002). A party responding to a motion for accelerated decision must produce *some* evidence which places the moving party's evidence in question and raises a question of fact for an adjudicatory hearing. *Id.* at 22-23; *see In re Bickford, Inc.*, Docket No. TSCA-V-C-052-92, 1994 TSCA LEXIS 90 (ALJ, November 28, 1994) (emphasis added).

The Supreme Court has noted, however, that there is no requirement that the moving party support its motion with affidavits negating the opposing party's claim or that the opposing party produce evidence in a form that would be admissible at trial in order to avoid summary judgment. *Celotex*, 477 U.S. at 323-324. The parties may move for summary judgment or successfully defeat summary judgment without supporting affidavits provided that other evidence referenced in Rule 56(c) adequately supports its position. Of course, if the moving party fails to carry its burden to show that it is entitled to summary judgment under established principles, then no defense is required. *Adickes*, 398 U.S. at 156.

The evidentiary standard of proof in the matter before me, as in all other cases of administrative assessment of civil penalties governed by the Rules of Practice, is a "preponderance of the evidence." 40 C.F.R. § 22.24. In determining whether or not there is a genuine factual dispute, I, as the judge and finder of fact, must consider whether I could reasonably find for the non-moving party under the "preponderance of the evidence" standard.

Accordingly, a party moving for accelerated decision must establish through the pleadings, depositions, answers to interrogatories, and admissions on file, together with any affidavits, the absence of genuine issues of material fact and that it is entitled to judgment as a matter of law by the preponderance of the evidence. On the other hand, a party opposing a properly supported motion for accelerated decision must demonstrate the existence of a genuine issue of material fact by proffering significant probative evidence from which a reasonable presiding officer could find in that party's favor by

a preponderance of the evidence. Even if a judge believes that summary judgment is technically proper upon review of the evidence in a case, sound judicial policy and the exercise of judicial discretion permit a denial of such a motion for the case to be developed fully at trial. *See Roberts v. Browning*, 610 F.2d 528, 536 (8th Cir. 1979).

## C. Discussion

At first blush, I see little merit to Respondent's legal arguments concerning its seven defenses/affirmative defenses. Nevertheless, in the context of an accelerated decision, I must view the evidentiary material and all reasonable inferences therefrom in the light most favorable to the non-moving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. at 255; *Adickes*, 398 U.S. at 158-59; *see also Cone v. Longmont United Hospital Assoc.*, 14 F.3d 526 at 528. Here, there is a genuine dispute as to the facts presented and the inferences drawn therefrom. Indeed, Complainant indirectly acknowledges competing interpretations of the facts in this matter, when Complainant summarizes its views of the interpretations "Respondent seems to be asserting" and the arguments that "Behnke could be making." *See* Mot. for Acc. Dec. at 50-54.

Moreover, contrary to Complainant's assertions, at the accelerated decision stage, Respondent need not support its defenses/affirmative defenses under a substantial evidence standard; rather, Respondent may demonstrate a genuine issue of material fact by proffering *some* material, relevant and probative evidence, which places the moving party's evidence in question and allows me to reasonably conclude by a preponderance of the evidence that a question of fact exists for an adjudicatory hearing. Mot. to Compel at 32; Resp. to Mot. for Acc. Dec. at 21. *See In the Matter of Strong Steel Products*, Docket Nos. RCRA-05-2001-0016, CAA-05-2001-0020, and NM-05-2001-0006, 2002 EPA ALJ LEXIS 57 at *22-23 (ALJ, September 9, 2002); *In re Bickford, Inc.*, Docket No. TSCA-V-C-052-92, 1994 TSCA LEXIS 90 (ALJ, November 28, 1994). *See also* 40 C.F.R. § 22.24. To defeat a motion for accelerated decision, the non-moving party must show more than a scintilla of evidence that could allow a reasonable fact-finder to rule in the non-movant's favor. *See Rogers Corporation v. EPA*, 275 F.3d 1096 (D.C. Cir. 2002) (To prevail on a motion for accelerated decision, the EPA initially must show that it has established the elements of liability and that there is an absence of evidence in the record for a respondent's affirmative defense; the respondent may then defeat EPA's motion by identifying specific facts that could allow a reasonable fact-

finder to find in Respondent's favor). Here, Respondent has provided some evidence and supporting affidavits to show the existence of a genuine issue of material fact warranting an evidentiary hearing. While it may be that Respondent barely meets this standard, it meets it nonetheless.

Thus, I find that a genuine issue of material fact exists in the instant matter and that fully developing the issues within the context of a hearing is more appropriate than accelerated decision.[14] Thus, Complainant's Motion for Accelerated Decision is **DENIED** as to all eleven counts alleged in the Complaint and as to Respondent's defenses/affirmative defenses.

I note that Respondent has made several admissions that will lessen Complainant's burdens at the hearing and likewise expedite the hearing. For instance, Respondent has admitted Behnke is a "person" "in any state" within the meaning of Section 2(s) of FIFRA, 7 U.S.C. § 136(s). Answer ¶ 13; Resp. to Mot. for Acc. Dec. at 11. Additionally, Respondent has admitted that it distributed, offered for sale, or sold, its products on the dates respectively alleged in each of the eleven counts of the Complaint. Resp. to Mot. for Acc. Dec. at 11-12. Respondent has also admitted that Behnke's Lubricants are not "registered" as pesticides under FIFRA, and that it does not dispute the allegations in the Complaint as they relate to the Lubricants' labels, Product Data Sheets, and literature that the Region discovered in its investigation. *Id.* at 12. Therefore, Complainant need not submit any additional evidence on these matters at the hearing. *See* Mot. for Acc. Dec. at 3.

## Conclusion

To summarize, I rule as follows:

Complainant's Motion to Strike: DENIED.

Complainant's Motion to Compel: GRANTED, IN PART, DENIED, IN PART

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[14] As noted, *supra*, even if I were to find that accelerated decision is technically proper upon review of the evidence in this case, sound judicial policy and the exercise of judicial discretion permit a denial of such a motion for the case to be developed fully at trial. *See Roberts v. Browning*, 610 F.2d 528 at 536.

Complainant's Motion for Accelerated Decision: DENIED

With regard to the Order on Complainant's Motion for Accelerated Decision, I emphasize that such denial does not decide the ultimate truth of the matter, but represents a threshold determination that an evidentiary hearing is shown to be warranted.

Dated: March 5, 2008
Washington, DC

Barbara A. Gunning
Administrative Law Judge

In the Matter of *Behnke Lubricants, Inc.*, Respondent.
Docket No. FIFRA-05-2007-0025

CERTIFICATE OF SERVICE

I certify that the foregoing **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**, dated March 5, 2008, was sent this day in the following manner to the addressees listed below.

Mary Angeles
Legal Staff Assistant

Original and One Copy by Facsimile and Pouch Mail to:

Sonja Brooks-Woodard
Regional Hearing Clerk
U.S. EPA, Region V, MC-13J
77 West Jackson Blvd., 13th Floor
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**Dated: March 5, 2008**
**Washington, D.C.**