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

REPLY TO THE ATTENTION OF:

POUCH MAIL

January 16, 2008

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

Re: *In the Matter of Behnke Lubricants, Inc.*
Docket No. FIFRA-05-2007-0025
Complainant's Motion to Strike Respondent's Affirmative Defenses, and Complainant's Motion to Compel Discovery

Dear Judge Gunning:

Enclosed, please find true, accurate and complete copies of Complainant's Motion to Strike Respondent's Affirmative Defenses, and Complainant's Motion to Compel Discovery. The original and one true, accurate and complete copy of Complainant's Motion to Strike Respondent's Affirmative Defenses, and Complainant's Motion to Compel Discovery were filed with the Regional Hearing Clerk, Region 5, U.S. EPA, on January 16, 2008. A true, accurate and complete copy of Complainant's Motion to Strike Respondent's Affirmative Defenses, and Complainant's Motion to Compel Discovery was delivered to Respondent's counsel via Federal Express on January 16, 2008.

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

Sincerely,

James J. Cha
Associate Regional Counsel

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

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	
	)	
BEHNKE LUBRICANTS, INC.	)	**ORDER ON DISCOVERY**
MENOMONEE FALLS, WISCONSIN	)	
	)	**Docket No. FIFRA-05-2007-0025**
Respondent.	)	
	)	

ORDER ON DISCOVERY

Respondent is hereby ordered to supplement its prehearing exchange to include the following information:

1. True, accurate and complete copies of all documentation or communications 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, or concerning any lubricants containing Micronox, including but not limited to the following agencies: the United States Food and Drug Administration (FDA); the United States Department of Health and Human Services (DHHS); and the U.S. EPA, Antimicrobial Division in the office of Pesticides Program (OPP).

2. A complete and accurate list of the chemical components of each of the following 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, by chemical name and by C.A.S. Number. Should Respondent wish to have this information protected as trade secrets or confidential business information, appropriate safeguards against unauthorized disclosure will be implemented in accordance with 40 C.F.R. Part 2.

3. True, accurate and complete copies of all documents that specifically describe the intended uses of Behnke's products (including but not limited to all correspondence with customers, and all advertising and technical literature).

4. A complete and detailed explanation of how "Behnke's products are strictly regulated by the Food & Drug Administration," and true, accurate and complete copies of all documents that substantiate such "strict regulation," including but not limited to the following types of documents: all correspondence between Behnke and the FDA concerning Behnke's products or the Micronox technology; all documents reflecting laboratory tests or other data which demonstrate the efficacy of Behnke's products as antimicrobials; all documents reflecting laboratory tests or other data which demonstrate the safety of Behnke's products; and all documents submitted by Behnke to the FDA with respect to its products or the Micronox technology. If documents responsive to this request do not exist, Respondent must state affirmatively that no such documents exist.

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 regarding 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 that were submitted to the Food and Drug Administration or the Dept. of Health and Human Services (DHHS) pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).

6. True, accurate and complete copies of all documents containing the following information:

a. The identity of the lubricant/food contact substance.

b. The intended use of the lubricant/food contact substance.

c. Behnke's determination that the intended use of the lubricant/food contact substance was safe in accordance with Section 409(c)(3)(A) of the FFDCA.

d. All supporting information that forms the basis of such a determination and all information required to be submitted by the applicable regulations implemented by the FFDCA.

e. If such notifications do not exist, an explanation of its absence for each lubricant listed above, and all supporting documentation.

7. A complete and accurate statement explaining how Behnke's Micronox 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, can be safely used on machinery that is used for packing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

8. A statement specifying whether each product can be used safely because the lubricants are prepared from one or more of the following substances:

a. The substances are generally recognized as safe for use in food. Provide supporting documentation.

b. The substances are used in accordance with the provisions of a prior sanction or approval. Provide supporting documentation.

c. The substances are identified in 21 C.F.R. Section 178.3570(a)(3). Provide supporting documentation.

9. A statement identifying the specific substances in each lubricant that fall in each category listed in 8.a – c, above.

10. True, accurate and complete copies of all documentation and communications between Behnke and NSF International regarding any Behnke lubricants containing Micronox, including 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; 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 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. Responsive documents must include, but are not limited to, the following:

a. True, accurate and complete copies of all NSF registration applications and responses for the above-named lubricants.

b. True, accurate and complete copies of all communications between Behnke and NSF regarding label changes that were needed for each of the above-named lubricants.

c. True, accurate and complete copies of all formulation data that was submitted to NSF for each of the above-named lubricants for the purpose of registration.

d. True, accurate and complete copies of all labels that were submitted to NSF for the above-named lubricants for the purpose of registration.

e. True, accurate and complete copies of all submissions of intended use classification and category code for each of the lubricants.

f. True, accurate and complete copies of all information relating to the listing of these lubricants in NSF's White Book listing.

g. True, accurate and complete copies of all registration letters for each of the above-named lubricants.

h. True, accurate and complete copies of all labels submitted to NSF on or after January 1, 2002 relating to the above-named lubricants.

i. True, accurate and complete copies of all advertising and print media on Behnke's website that resulted after the registration of these lubricants by NSF.

j. True, accurate and complete copies of all communications between Behnke and NSF in 2002 through 2005 regarding language changes on the labels of the above-named lubricants.

k. True, accurate and complete copies of all communications between Behnke and NSF that relates to NSF requesting that Behnke seek approval from the U.S. EPA to register Micronox lubricants and to label and identify the Micronox lubricants as pesticides.

l. True, accurate and complete copies of all court documents and communications between Behke and NSF as a result of the declaratory judgement filed by Behnke against NSF relating to the registration of Micronox lubricants such as 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, Case No. 2:06-cv-00353-RTR, Waukesha County Case Co. 06CV134.

m. True, accurate and complete copies of all documents reflecting product names;

n. A statement providing the qualitative and quantitative (percentage of weight) identification of all constituents of each Behnke product at issue in the Complaint;

o. The Chemical Abstract Service (CAS) number, if applicable, for each constituent of each Behnke product at issue in the Complaint;

p. The chemical ingredient names based on the International Union of Pure and Applied Chemistry (UPAC) rules, for each constituent of each Behnke product at issue in the Complaint;

q. A statement identifying all suppliers or sources of each ingredient in each Behnke product at issue in the Complaint;

r. True, accurate and complete copies of all prior product regulatory approvals from any state or country regulatory authority for each Behnke product at issue in the Complaint;

s. The appropriate FDA regulatory reference for each ingredient in each Behnke product at issue in the Complaint (as found in 21 CFR Sections 178.3570, 172.860 and 172.878);

t. A true, accurate and complete copy of the product label submitted to NSF along with the registration application for each Behnke product at issue in the Complaint; and

u. True, accurate and complete copies of all notifications, if any, submitted to NSF as a result of changes to the registered formulations of each Behnke product at issue in the Complaint.

11. A statement clarifying how 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, 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 affirmative defense number 6. If such contaminants are microorganisms, the statement must include an explanation as to how Behke complied with the treated article exemption pursuant 40 CFR Section 152.25.

13. A statement identifying the antimicrobial additive that is in each of the following 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, by chemical name, C.A.S. Number and EPA Registration number.

14. A statement providing context for RX 54 ("Behnke Publication regarding food grade lubricant certification"), including an explanation as to what the document is, who created it, when it was created, why it was created, to whom and when it was distributed, and why it was distributed.

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, as required by the June 27, 2007, Prehearing Order.

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. § 136l(a)(4).

17. A statement clarifying the relationship between Xact Fluid Solutions and Behnke, including an explanation of whether Xact Fluid Solutions is a subsidiary or an operating division of Behnke, and what services or products are provided by Xact Fluid Solutions on behalf of Behnke.

18. Revised narrative summaries of the expected testimony of Respondent's witnesses, specifically including the information and documents requested in Complainant's Motion.

So Ordered.

_____

Honorable Barbara A. Gunning
Administrative Law Judge

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	
	)	
BEHNKE LUBRICANTS, INC.	)	**COMPLAINANT'S MOTION TO**
MENOMONEE FALLS, WISCONSIN	)	**STRIKE RESPONDENT'S**
	)	**AFFIRMATIVE DEFENSES, AND**
Respondent.	)	**COMPLAINANT'S MOTION TO**
	)	**COMPEL DISCOVERY**
	)	
	)	**Docket No. FIFRA-05-2007-0025**

COMPLAINANT'S MOTION TO STRIKE RESPONDENT'S AFFIRMATIVE DEFENSES, AND COMPLAINANT'S MOTION TO COMPEL DISCOVERY

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	
	)	
BEHNKE LUBRICANTS, INC.	)	**COMPLAINANT'S MOTION TO**
MENOMONEE FALLS, WISCONSIN	)	**STRIKE RESPONDENT'S**
	)	**AFFIRMATIVE DEFENSES, AND**
Respondent.	)	**COMPLAINANT'S MOTION TO**
	)	**COMPEL DISCOVERY**
	)	
	)	**Docket No. FIFRA-05-2007-0025**

COMPLAINANT'S MOTION TO STRIKE RESPONDENT'S AFFIRMATIVE DEFENSES, AND COMPLAINANT'S MOTION TO COMPEL DISCOVERY

Complainant, through its undersigned attorney, files the instant Complainant's Motion to Strike Respondent's Affirmative Defenses, and Complainant's Motion to Compel Discovery ("Motion") pursuant to the authority of Sections 22.15, 22.16, 22.19(a)(2), 22.19(e) and 22.20 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits, ("Consolidated Rules" or "CROP") 40 C.F.R. §§ 22.15, 22.16, 22.19(a)(2), 22.19(e) and 22.20. As indicated below, Complainant requests that this Honorable Court issue an Order striking certain of Respondent's affirmative defenses[1] because these defenses are insufficient as a matter of law, and there is no possibility that they can relieve Respondent of its liability for the violations alleged in the Complaint.

[1] In its Answer to the Complaint, Respondent lists seven "Affirmative Defenses' on pages 27-28. It is not clear whether each of these asserted defenses in fact meets the standard for "affirmative defenses." *See, e.g., In the Matter of USA Remediation Services*, 2003 EPA ALJ LEXIS 6 (February 10, 2003), Order on Motions ("An affirmative defense is an assertion by a respondent raising new facts and arguments that, if true, will defeat the Complainant's claim, even if all allegations in the complaint are true."). For simplicity, Complainant will refer to these defenses as "affirmative defenses" in the instant motion.

In addition, Complainant requests this Court to order Respondent, Behnke Lubricants, Inc. (Behnke), to submit certain documents and to provide other information relevant to each of Behnke's asserted defenses.[2]

I. Background

On May 7, 2007, Complainant filed a civil administrative Complaint against Respondent, Behnke Lubricants, Inc. (Behnke), alleging the sale or distribution of unregistered pesticides in violation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In general, Complainant alleged eleven instances of Respondent selling or distributing the following Behnke lubricant products: 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. The Complaint further alleged that the labeling or advertising literature for these products claimed, stated or implied that each of these products was a pesticide within the meaning of FIFRA, because such labeling and advertising literature claimed, stated or implied that each of the products was effective against micro-organisms such as Listeria monocytogenes (Listeria), Escherichia coli (E. coli) and Salmonella typhimurium (Salmonella), which are considered "pests" within the meaning of FIFRA.

On or about June 8, 2007, Respondent filed its Answer to the Complaint. In its Answer, Respondent denied that the products which it had sold or distributed were

[2] This discovery motion applies to five of Behnke's seven asserted affirmative defenses. Where Complainant has moved to strike a particular defense for which it is also seeking discovery, the discovery motion should be treated as an alternative request for relief. Should the motion to strike any affirmative defense be granted by this Court, the motion for discovery of information relevant to that defense should be considered moot.

pesticides within the meaning of FIFRA, and raised the following seven "Affirmative Defenses":

> 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). Behnke's products are approved as lubricants with incidental food contact pursuant to 21 CFR 178.3570, a regulation promulgated pursuant to 21 U.S.C. §348(a). It is anticipated that such products will be subject to incidental food contact and ingestion. As such, Behnke's products are strictly regulated by the Food & Drug Administration 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. 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.
>
> 7. Behnke's products are not intended for a pesticidal purpose as set forth in 40 CFR §152.15, i.e., they are not intended to be used for the purpose of preventing, destroying, repelling or mitigating any pest. A "pest" as defined in 40 CFR §152.5, does not include microorganisms on or in processed food, which are the environmental contaminants to which Behnke's products are exposed.

See Answer, pp. 27-28.

On June 21, 2007, Complainant filed with the Regional Hearing Clerk and served on Respondent's counsel a document entitled *Notice of Complainant's Request for Voluntary Production of Information.* In this document, Complainant specifically

requested that Respondent produce in its prehearing exchange, *inter alia*, the following categories of information relevant to the affirmative defenses raised in Behnke's Answer:

1. In connection with all of Respondent's defenses (which claimed that the lubricant products at issue are not pesticides), Complainant requested the following information:

> Any and 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, including but not limited to:
>
> a. The United States Food and Drug Administration (FDA).
> b. The United States Department of Health and Human Services (DHHS).
> c. The U.S. EPA, Antimicrobial Division in the office of Pesticides Program (OPP) concerning any lubricants containing Micronox."

See Notice of Complainant's Request for Voluntary Production of Information, pp. 2-3.

2. In connection with Respondent's "Affirmative Defense" number 5 (which asserted that Behnke's lubricants are not "pesticide chemicals" but rather are "food additives," as defined by the FFDCA), Complainant requested "all notifications submitted to the [Dept. of Health and Human Services (DHHS)] pursuant to the [Federal Food, Drug and Cosmetic Act (FFDCA)] to support affirmative defense 5." *See Notice of Complainant's Request for Voluntary Production of Information*, p. 3. Complainant specifically requested "[a]ny and all notifications submitted to the Secretary of the DHHS regarding 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, in compliance with Section 409(h) of the Federal Food, Drug and Cosmetics Act (FFDCA)," including but not limited to:

a. The identity of the lubricant/food contact substance.
b. The intended use of the lubricant/food contact substance.
c. Behnke's determination that the intended use of the lubricant/food contact substance was safe in accordance with Section 409(c)(3)(A) of the FFDCA.
d. All supporting information that forms the basis of such a determination and all information required to be submitted by the applicable regulations implemented by the FFDCA.
e. If such notifications do not exist, an explanation of its absence for each lubricant listed in paragraph 2. Provide supporting documentation."

See Notice of Complainant's Request for Voluntary Production of Information, p. 3.

4. In connection with affirmative defense 5 (in which Respondent asserted that the lubricants in question are approved as lubricants with incidental food contact pursuant to 21 C.F.R. 178.3570), Complainant requested the following information:

> Pursuant to 21 C.F.R. Section 178.3570, indicate how Behnke's Micronox 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, can be safely used on machinery used for packing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.
> a. Specify if each product can safely be used because the lubricants are prepared from one or more of the following substances:
>
> i. The substances are generally recognized as safe for use in food. Provide supporting documentation.
> ii. The substances are used in accordance with the provisions of a prior sanction or approval. Provide supporting documentation.
> iii. The substances are identified in 21 C.F.R. Section 178.3570(a)(3). Provide supporting documentation.
>
> b. Specify the specific substances in each lubricant that fall in each category listed in 3.a. above.

5. Also in connection with affirmative defense 5, Complainant provided the following relevant background information:

> For these types of lubricants, the United States Department of Agriculture (USDA) created the original food-grade designation H1, H2, and H3 in which it would approve

> lubricants and its registration in one of these categories based on the list of ingredients. Since September 30, 1998, the USDA stopped issuing registrations of food-grade lubricants and NSF International (NSF) evolved to succeed the USDA registration roles of food-grade lubricants for these types of lubricants. Behnke has registered the lubricants in question with NSF.

See Notice of Complainant's Request for Voluntary Production of Information, pp. 4-5.

Therefore, Complainant specifically requested the following information:

> Provide any and all documentation and communication between Behnke and NSF International regarding any Behnke lubricants containing Micronox, including 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, including but not limited to:
>
> a. NSF registration applications and responses for the above-named lubricants.
>
> b. Any communication between Behnke and NSF regarding label changes that were needed for each of the above-named lubricants.
>
> c. Any formulation data that was submitted to NSF for each of the above-named lubricants for the purpose of registration.
>
> d. Any labels that were submitted to NSF for the above-named lubricants for the purpose of registration.
>
> e. Submissions of intended use classification and category code for each of the lubricants.
>
> f. Any information relating to the listing of these lubricants in NSF's White Book listing.
>
> g. Registration letters for each of the above-named lubricants.
>
> h. All labels submitted to NSF on or after January 1, 2002 relating to the above-named lubricants.
>
> i. Copies of all advertising and print media on Behnke's website that resulted after the registration of these lubricants by NSF.
>
> j. Any communication between Behnke and NSF in 2002 through 2005 regarding language changes on the labels of the above-named lubricants.
>
> k. Any communication between Behnke and NSF that relates to NSF requesting that Behnke seek approval from the U.S. EPA to register Micronox lubricants and to label and identify the Micronox lubricants as pesticides.
>
> l. Any court documents and communications between Behke and NSF as a result of the declaratory judgement filed by Behnke against NSF relating to the registration of Micronox lubricants such as 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, Case No. 2:06-cv-00353-RTR, Waukesha County Case Co. 06CV134.

See Notice of Complainant's Request for Voluntary Production of Information, pp. 5-6.

Complainant also requested the following information in connection with NSF evaluation requirements:

> any and all documentation submitted to NSF so that NSF could complete its evaluation requirements for 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, including but not limited to:
> m. Product name;
> n. A qualitative and quantitative (percentage of weight) identification of all constituents;
> o. The Chemical Abstract Service (CAS) number, if applicable;
> p. The chemical ingredient names based on the International Union of Pure and Applied Chemistry (UPAC) rules;
> q. Suppliers or sources of each ingredient;
> r. Prior product regulatory approval from any state or country regulatory authority;
> s. Appropriate FDA regulatory reference for each ingredient in 21 CFR Sections 178.3570, 172.860 and 172.878;
> t. A copy of the product label submitted to NSF along with the registration application; and
> u. Any notifications, if any, submitted to NSF as a result of changes to the registered formulations.

See Notice of Complainant's Request for Voluntary Production of Information, p. 6.

6. In connection with affirmative defenses 1, 2 and 7 (in which Behnke asserted that the lubricants in question are not "pesticides" within the meaning of FIFRA, that the lubricants do not contain "pesticides," that the lubricants are not intended for a pesticidal purpose, and that the micro-organisms targeted by these products are not "pests" within the meaning of FIFRA), Complainant noted that "the chemical components of the lubricants may become relevant to determine if there are active ingredients that are known pesticides or have known pesticidal properties in the lubricants." *See Notice of Complainant's Request for Voluntary Production of*

Information, pp. 6-7. Therefore, Complainant specifically requested the following information: "a list of the chemical components of each of the following 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, by chemical name and by C.A.S. Number." *See Notice of Complainant's Request for Voluntary Production of Information*, p. 7.

7. In connection with affirmative defense 6 (in which Respondent asserted that the lubricants in question "are formulated to resist internal degradation from contaminants found in food processing environments."), Complainant requested the following information:

> a. Clarify how Behnkes 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, are formulated to resist internal degradation from contaminants found in food processing environments.
>
> b. Specify the contaminants that Behnke is referring to in paragraph 6 of its affirmative defenses. If such contaminants are microorganisms, explain how Behke complied with the treated article exemption pursuant 40 CFR Section 152.25.
>
> c. Identify the antimicrobial additive that is in each of the following 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, by chemical name. C.A.S. Number and EPA Registration number.

See Notice of Complainant's Request for Voluntary Production of Information, p. 7.

On October 4, 2007, Complainant filed its Initial Prehearing Exchange.

On or about November 10, 2007, Respondent submitted its Prehearing Exchange (PHX). In this Prehearing Exchange, Respondent failed to submit any of the information pertaining to its affirmative defenses that Complainant had requested nearly five (5)

months earlier in its *Notice of Complainant's Request for Voluntary Production of Information.*

On or about November 15, 2007, Complainant filed its Rebuttal Prehearing Exchange. In that document, Complainant renewed its request for the information identified in its June 21, 2007, *Notice of Complainant's Request for Voluntary Production of Information. See Complainant's Rebuttal Prehearing Exchange*, p. 6. In addition, Complainant requested the following information:

> *III. Seeking Clarification on the Following Matters*
>
> *a. Complainant requests that Respondent provide context for RX 54, including an explanation as to what the document is, who created it, when it was created, why it was created, to whom and when it was distributed, and why it was distributed.*
>
> *b. Complainant requests that Respondent specify the estimated amount of time needed to present its case-in-chief, as required by this Court's June 27, 2007, Prehearing Order.*
>
> *c. Complainant requests that Respondent submit a statement affirmatively stating 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, as required by the June 27, 2007, Prehearing Order.*
>
> *d. Complainant renews its request for Respondent to either produce complete and reliable evidence of its actual gross sales, or expressly waive any objection to the penalty based on the "size of business" statutory penalty factor. As an alternative, Respondent can stipulate that the amount of its annual gross sales exceeds one-million dollars ($1,000,000).*
>
> *e. Complainant requests that Respondent provide greater detail in its narrative summaries for its witnesses. In addition, Complainant does not believe that the described testimony of several of the witnesses identified in Respondent's prehearing exchange is relevant to any issues relating to either liability or the amount of the penalty. Therefore, Complainant requests that Respondent explain how the testimony of each of the following witnesses relates to the alleged*

distribution or sale of unregistered products as set forth in the Complaint, or to any defenses or arguments concerning the proposed penalty.

i. Mr. Carter Anderson
ii. Ms. Patty Riek
iii. Mr. Shaun Beauchamp

A follow-up Motion may be submitted regarding this matter.

f. Respondent identifies an expert witness who will testify to "background information regarding customer demands and requirements that lead [sic] to the investment in research and development of this technology including testing that demonstrated the antimicrobial properties of the additives."

Complainant does not believe that this proposed testimony, as described, is relevant to any issues relating to either liability or the amount of the penalty. Therefore, Complainant requests that Respondent explain how this testimony is relevant to the alleged distribution or sale of unregistered pesticides as set forth in the Complaint, or to any defenses or arguments concerning the proposed penalty.

In the event that such testimony is deemed relevant by this Court, Complainant requests that Respondent produce all of the testing data generated with respect to the "testing that demonstrated the antimicrobial properties of the additives" in the Behnke products at issue in the Complaint. Such testing data should include, but not be limited to, all laboratory analytical reports, all raw data, all test methods used, all Quality Assurance and Quality Control plans followed by the laboratory, all standard operating procedures followed by the laboratory, and all chain-of-custody forms. A follow up Motion may be submitted regarding this matter.

g. Complainant requests that Respondent provide clarification on the relationship between Xact Fluid Solutions and Behnke.

h. Complaint renews its Notice of Complaint's Request For Voluntary Production of Information, which was filed on July 19, 2007. In the alternative, Complainant requests that Respondent withdraw the affirmative defenses set forth in its Answer to the Complaint, dated June 8, 2007. A follow up Motion for discovery or motion to strike affirmative defenses may be submitted regarding this matter.

See Complainant's Rebuttal Prehearing Exchange, at 4-6.

On December 11, 2007, Respondent filed its Supplemental Prehearing Exchange. Other than providing the estimated amount of time needed to present its case-in-chief, Respondent did not provide any of the information requested by Complainant. To date, Behnke has not furnished any additional information to Complainant, and Complainant now moves for discovery of the information identified below.

II. Summary of Argument

While it is rare for a court to grant a motion to strike defenses, doing so in the instant matter is appropriate. Following an examination of the statutes and regulations cited by Respondent in support of its affirmative defenses 3, 4, 5 and 6, Complainant believes that these defenses are legally insufficient as defenses against liability, regardless of any facts that Respondent may be able to establish at hearing. Respondent has failed to make any reference to these defenses in a "statement explaining why the proposed penalty should be reduced or eliminated," which statement was specifically ordered in this Court's Prehearing Order of June 27, 2007. In fact, Respondent has provided no such statement arguing for reduction or elimination of the penalty.

Under the standards applicable to motions to strike, these four affirmative defenses should be stricken at this time. *See, e.g., Heller Financial, Inc. v. Mid-Whey Powder Co.*, 883 F.2d 1286, at 1294 (7th Cir. 1989) ("where, as here, motions to strike remove unnecessary clutter from the case, they serve to expedite, not delay"); *and In the Matter of Strong Steel*, 2003 EPA ALJ LEXIS 191 (October 27, 2003), Order on Motions ("[a]n affirmative defense is legally 'insufficient' if, as a matter of law, it cannot succeed under any circumstances"). For the reasons set forth below, Complainant hereby moves this Honorable Court to issue an Order striking each of these four affirmative defenses.

Largely as an alternative prayer for relief, Complainant also requests that the Court issue the attached discovery order (including discovery of information relevant to the four affirmative defenses which Complainant has moved to strike, but only in the event that the Court decides not to grant Complainant's motion to strike these affirmative defenses). If the information identified in the attached discovery order is not provided to Complainant and the Court by the deadline specified in the discovery order, Complainant requests that this Court issue an Order barring Respondent from proffering any testimony or other evidence relating to any of Respondent's affirmative defenses, and also striking all seven "Affirmative Defenses." *See In the Matter of 1836 Realty Corp.*, Dkt. No. CWA-2-I-9, 1999 EPA ALJ LEXIS 113 (April 8, 1999) (Order Granting Complainant's Motion to Strike) (holding that, under 40 C.F.R. § 22.19(f)(4), failure to comply with a discovery order for information relevant to a defense may lead to the inference that the information to be discovered would have been adverse to the party from whom the information was sought, and precluding Respondent from raising the defense).

III. Respondent's Affirmative Defenses 3, 4, 5 and 6 Should Be Stricken as Legally Insufficient

While motions to strike are generally disfavored by courts, this view is premised on the observations that striking a portion of a pleading is a drastic remedy, and that such motions potentially serve only to delay the proceedings.[3] However, federal courts and decisions by Administrative Law Judges have recognized that, where a defense is insufficient as a matter of law, a motion to strike actually serves to avoid delay, and should be granted. *See Heller Financial, Inc. v. Mid-Whey Powder Co.*, 883 F.2d at

[3] *See United States v. 416.81 Acres of Land*, 514 F.2d 627, 631 (7th Cir. 1975) (Clark, J.).

1294-95 (7th Cir. 1989) (affirming district court decision to strike affirmative defenses that were without merit and insufficient as a matter or law); *and Fabrica Italiana Lavorazione Materie Organiche, S.A.S. v. Kaiser Aluminum*, 684 F.2d 776, at 779-80 (11th Cir. 1982) (affirming district court's decision to strike affirmative defense that was "legally insufficient" in the context of the case before the court). As this Court has noted, "[m]otions to strike . . . 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 (ALJ, Jan. 3, 2003).

In the instant matter, each of the affirmative defenses identified above is insufficient as a matter of law, at least in relation to the issue of Respondent's liability.[4] It is therefore unnecessary for this Court to engage in the time-consuming task of fact-finding in an evidentiary hearing on these defenses. None of Respondent's affirmative defenses 3 through 6 have any legal affect on Respondent's liability for the violations of FIFRA alleged in the Complaint. The assertions, even if assumed to be true, fail to relieve Behnke of its liability under Section 12 of FIFRA, 7 U.S.C. § 136j, for the sale or distribution of unregistered pesticides. Therefore, this Court should strike these four affirmative defenses before hearing.[5]

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[4] Based on Respondent's Answer to the Complaint, each of the Affirmative Defenses listed on pages 27-28 of the Answer has been raised as a defense to liability, not as a mitigating factor pertaining to the issue of penalties. Under 40 C.F.R. § 22.15(c), a hearing is to be held "upon the issues raised by the complaint and answer." Because Respondent has not asserted any of these Affirmative Defenses as mitigating factors relevant to the issue of penalties, the Affirmative Defenses should be treated as defenses to liability only. As explained further below, each of Respondent's asserted Affirmative Defenses discussed herein is insufficient as a matter of law, and should be stricken to avoid the unnecessary expenditure of judicial resources in a lengthy evidentiary hearing on what are in fact purely legal arguments.

[5] Complainant intends to file a separate motion for partial accelerated decision as to Respondent's liability for the violations alleged in the Complaint. In such motion, Complainant will argue that there are no

A. Respondent's Third Affirmative Defense

Respondent's third affirmative defense asserts that "Behnke's products are not "antimicrobial pesticides" within the meaning of 7 U.S.C. §136(mm)." This assertion is irrelevant to the issue of Respondent's liability for the sale/distribution of unregistered pesticides under FIFRA. Whether or not any of Behnke's products meets the definition of "antimicrobial pesticide" has no bearing on whether such product is a "pesticide" within the meaning of FIFRA.

Respondent's argument appears to be that, if a substance is an antimicrobial product, but it does not meet the definition of "antimicrobial pesticide" found in Section 2(mm) of FIFRA because it is subject to "a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a and 348) or a food additive regulation under section 409 of such Act," then the substance cannot be a "pesticide" under Section 2(u) of FIFRA. However, this argument distorts the plain language of the FIFRA statute, and is contradicted by both the logical structure of the Act and its legislative history.

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). See Pub.L. 104-170, § 221(2). The definition reads as follows:

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genuine issues of material fact with respect to Respondent's liability; as part of this argument, Complainant will point out that there are no genuine issues of material fact with respect to any of Respondent's Affirmative Defenses. Complainant believes that, with respect to Affirmative Defenses 1, 2 and 7, a motion for accelerated decision is more appropriate than a motion to strike to resolve the legal issues raised by these particular defenses. *See In the Matter of Harpoon Partnership*, Docket No. TSCA-05-2002-0004, 2003 EPA ALJ LEXIS 52, Order Granting Complainant's Request for Partial Accelerated Decision (August 4, 2003), aff'd. *In Re: Harpoon Partnership*, 12 E.A.D. 182, at 190 (2005) (explaining procedural history in which Complainant filed motion to strike an affirmative defense, and ALJ directed the parties to submit briefs addressing the legal questions raised by this affirmative defense, and subsequently issued partial accelerated decision resolving such issues in "Order Granting Complainant's Request for Partial Accelerated Decision and Denying Respondent's Request for Partial Accelerated Decision").

Section 136(mm) Antimicrobial Pesticide.

(1) In general.

The term "antimicrobial pesticide" means a pesticide that--
(A) is intended to—

(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or

(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a and 348) or a food additive regulation under section 409 of such Act.

7 U.S.C. § 136(mm). See 142 Cong. Rec. H 8127, 8131 (Tuesday, July 23, 1996). 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 lead to the establishment of deadlines for the registration of antimicrobial products that met the definition of "antimicrobial pesticide" set forth in Section 2(mm) (hereinafter referred to as "Section 2(mm) antimicrobial pesticide(s)"). This new section was entitled "Registration Requirements for Anti-microbial Pesticides," and it required U.S. EPA to "identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products." 7 U.S.C. § 136a(h)(1). Section 3(h) also specified that the "reforms" mandated under this legislation "shall be designed to achieve the goal of reducing the review period following submission of a complete application [for registration of an antimicrobial pesticide]," and established definite time periods within which such reviews of applications were to be

completed. 7 U.S.C. § 136a(h)(2). See 142 Cong. Rec. H 8127, 8131-32. 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), and this indicates that the only purpose of this amendment was to provide for expedited review of registration applications submitted for Section 2(mm) antimicrobial pesticides. Nothing in the statute suggests that Section 2(mm) was intended to limit in any way the scope of FIFRA's regulatory coverage, nor does any language in the amendments to FIFRA suggest that Section 2(mm) somehow affected the broad definition of "pesticide" set forth in Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

Moreover, the legislative history of the FQPA reveals that the purpose of the amendment which added Section 2(mm) (the definition of "antimicrobial pesticide") to FIFRA was to create an expedited process for U.S. EPA's review of FIFRA registration applications for certain antimicrobial products. For example, the House Committee Report for the FQPA, House Rept. 669, Part 1, includes the following discussion:

> Pesticides utilized for the control of microorganisms in restaurants, hospitals, and institutions for sanitation reasons are indispensable. Protection against the presence and growth of microorganisms capable of food borne illness or spread of nosocomial infections need to be addressed through a diverse and efficacious arsenal of antimicrobial sanitizers. The antimicrobial pesticide registration process has been patterned after the process utilized for agricultural pesticides. *The registration of antimicrobial pesticides have been plagued with inefficiencies and unnecessary delays. In order to improve upon the registration of antimicrobial pesticides and how those registrations are managed, the bill provides a definition for these important products and improves the registration efficiency by recognizing their unique purpose compared to that of other pesticide products. ...*

1996 Committee Reports, July 11, 1996, 104 H. Rpt. 669 (emphasis added), reprinted in 1996 U.S. Code Cong. & Adm. News, p. 1214. A related bill introduced in the Senate in

1995 discussed the "significant and unintended delays" in the process of registration of antimicrobial products under FIFRA. 141 Cong. Rec. S. 19009 (Wednesday, December 20, 1995). This legislative history reveals that, when Congress drafted Section 2(mm) of FIFRA, Congress was concerned with the lengthy delays in registration of antimicrobial products "utilized for the control of microorganisms in restaurants, hospitals, and institutions for sanitation reasons." There is nothing to suggest that Congress intended to reduce the scope of FIFRA regulatory coverage with respect to pesticides claimed to destroy or mitigate bacteria, viruses or other microorganisms, whether or not such pesticides fit within the specific definition of "antimicrobial pesticides" found in Section 2(mm).

Finally, it must be noted that the FQPA did not amend the definition of "pesticide" in Section 2(u) to provide an exclusion for antimicrobial products that were subject to a tolerance or food additive regulation under the FFDCA. Had Congress intended to amend the definition of "pesticide" to exclude from any regulatory coverage under FIFRA those antimicrobial products that did not meet the definition of Section 2(mm) antimicrobial pesticides, Congress most certainly would have amended the definition of "pesticide" in Section 2(u) to make that exclusion. That would have been the logical means of creating an exclusion of a substance from FIFRA jurisdiction. Other amendments to FIFRA effectuated by the passage of the FQPA reveal that Congress was not shy about expressly amending the statute to exclude products from FIFRA jurisdiction. Specifically, Congress amended the definition of "pesticide" in Section 2(u) of FIFRA as follows:

> The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such

> products) for use on a critical or semi-critical device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). For purposes of the preceding sentence, the term "critical device" includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term "semi-critical device" includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body."

7 U.S.C. § 136(u). The fact that Congress unambiguously excluded "liquid chemical sterilant products for use on a critical or semi-critical device" from the definition of "pesticide," yet did not draft a similar exclusion for those antimicrobial products which were subject to either a tolerance or a food additive regulation under the FFDCA, indicates that the FQPA was never intended to remove such antimicrobial products from the regulatory coverage of FIFRA. Clearly, when Congress passed the FQPA, it never intended to exclude antimicrobial products that were subject to the FFDCA from all regulatory coverage under FIFRA.

In September of 1999, U.S. EPA published a Federal Register notice in which it offered a reasonable explanation of the definition of "antimicrobial pesticide" set forth in Section 2(mm) of FIFRA. In a proposed rule that would have established specific registration requirements for antimicrobial pesticide products in order to implement Section 3(h) of FIFRA (antimicrobial registration), U.S. EPA offered the following explanation for Congress' decision to exclude from the definition of 2(mm) antimicrobial pesticides those antimicrobial pesticide products that were subject to a tolerance or a food additive regulation under the FFDCA:

> In creating this exclusion, Congress recognized that applications for registration of food uses that require clearance under FFDCA require extensive data and relatively complex risk assessments that take longer to review. Moreover, obtaining an FFDCA clearance is a formal regulatory procedure. As discussed in Unit VIII.H., FIFRA section 3(h) establishes

> goals for completion of Agency review of an application for registration [of 2(mm) antimicrobial pesticides]. In EPA's view, Congress recognized the difficulty of requiring the review timeframes for registration to encompass the complexities of FFDCA clearance as well. Accordingly, EPA believes that Congress intended the statutory definition to allow exclusion of any antimicrobial pesticide that would require the extensive clearance process of the FFDCA.

64 Fed. Reg. 50672, at 50677(September 17, 1999).

It is important to remember that U.S. EPA regulates pesticidal substances (including antimicrobials) under two separate statutes: FIFRA (which is the statute at issue in the instant case) and the FFDCA (which is not relevant to this case). A particular substance may meet both the definition of "pesticide" under FIFRA and the definition of "pesticide chemical" under the FFDCA; however, U.S. EPA will have a very different form of regulatory authority over that substance under FIFRA than it will under the FFDCA. Under FIFRA, U.S. EPA has broad regulatory coverage over any substance (including an antimicrobial substance) that meets the definition of "pesticide": U.S. EPA is responsible for registering pesticides, and the Agency brings enforcement actions for the sale or distribution of unregistered pesticides, and for other violations of FIFRA. In contrast, U.S. EPA has a much smaller regulatory role with respect to a substance that meets the definition of "pesticide chemical" under the FFDCA: under 21 U.S.C. § 346a(b), the Administrator of U.S. EPA "may issue regulations establishing, modifying, or revoking *a tolerance for a pesticide chemical residue* in or on a food." 21 U.S.C. § 346a(b)(1) (emphasis added).[6] The Administrator of U.S. EPA may also establish, modify or revoke exemptions from the requirement of a tolerance. 21 U.S.C. 346a(c).

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[6] The term "pesticide chemical residue" is defined in the FFDCA as "a residue in or on raw agricultural or processed food of -- (A) a pesticide chemical; or (B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical. See 21 U.S.C. 321(q)(2).

As explained in the 1999 Fed. Reg. notice quoted above, U.S. EPA believed that, because the process of obtaining an FFDCA clearance was unavoidably lengthy, and because antimicrobial pesticide products involving use around food would be subject to this cumbersome process, these types of antimicrobial pesticide products could not be registered as "pesticides" under FIFRA within the expedited timeframes set forth in Section 3(h) of FIFRA. Therefore, Congress made the pragmatic decision to exclude these types of antimicrobials (i.e., those subject to a food additive regulation or a tolerance under the FFDCA) from the definition of 2(mm) antimicrobial pesticides and the rigid timeframes for registration under Section 3(h) of FIFRA.

As noted in the legislative history of the FQPA, U.S. EPA was heavily involved in the decision-making process that led to the passage of the FQPA. See 142 Cong. Rec. H. 8127, at 8143 (comments by Rep. Dingell: "It is an amazing compromise that has been reached, which has brought together some of the most staunch and bitter rivals in this debate--consumer and environmental groups, the food industry, American agriculture, and the Federal Government agencies who oversee pesticide use and safety--the Environmental Protection Agency and the Food and Drug Administration."); 142 Cong. Rec. S. 8736, at 8737-38 (requesting publication in the record of three letters from Dr. Lynn Goldman, Assistant Administrator, Environmental Protection Agency). Therefore, U.S. EPA's regulatory interpretation of those provisions of the FQPA that amended FIFRA (including Section 2(mm)), as set forth in CX 23, should be viewed as highly persuasive.

B. Respondent's Fourth Affirmative Defense

Respondent's fourth affirmative defense makes the assertion that "Behnke's products are not "pesticide chemicals" within the meaning of 21 U.S.C. §321(q)(1)(A). The statutory provision cited by Respondent, 21 U.S.C. § 321(q)(1)(A) is part of the Federal Food, Drug and Cosmetic Act (FFDCA). The definition of "pesticide chemical" cited by Respondent was added to the FFDCA on October 21, 1998, as part of the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA), Pub.L. 105-324, §2(a). See 144 *Cong Rec E* 2280, at 2280-81 (October 21, 1998). This statutory citation in its entirety reads as follows:

> **321(q)(1)(A)** Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.
>
> (B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):
>
> (i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:
>
> (I) The substance is applied in the field.
>
> (II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

> (III) The substance is applied during the transportation of such commodity between the field and such a treat-ment facility.
>
> (ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 409(h)(6) [21 USCS § 348(h)(6)], and any of the following circum-stances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.
>
> With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.

21 U.S.C. § 321(q)(1). Respondent appears to be arguing that, because its products fall within one of the exemptions set forth in Section 321(q)(1)(B) ("clause (B)"), those products are not "pesticide chemicals" within the meaning of Section 321(q)(1)(A). However, whether or not Behnke's lubricant products are "pesticide chemicals" under the FFDCA is irrelevant as a matter of law. For even assuming that Behnke's lubricant products are not "pesticide chemicals" within the meaning of the 21 U.S.C. §321(q)(1)(A) by virtue of an exemption in Section 321(q)(1)(B), this has absolutely no bearing on whether the products are "pesticides" under FIFRA.

Again, it is important to remember that U.S. EPA's jurisdiction under the FFDCA is separate and distinct from U.S. EPA's jurisdiction under FIFRA. As explained above, under the FFDCA, U.S. EPA is authorized to "issue regulations establishing, modifying,

or revoking a tolerance for a pesticide chemical residue in or on a food." 21 U.S.C. § 346a(b)(1). The Agency's regulatory jurisdiction under the FFDCA is limited to substances that meet the definition of "pesticide chemical" under 21 U.S.C. § 321(q)(1)(A) of the FFDCA. If a substance is a "pesticide chemical," then U.S. EPA is authorized under the FFDCA to establish or modify or revoke a tolerance for residues of that substance in or on food. If the substance is a "food additive," then FFDCA regulatory coverage of that substance is handled by the FDA. See 21 U.S.C. § 321(q)(1)(B). In contrast, U.S. EPA has complete jurisdiction over any substance that meets the definition of "pesticide" set forth in Section 2(u) of FIFRA, 7 U.S.C. § 136j(u). The FDA plays absolutely no role in the enforcement of FIFRA, and FDA regulations therefore have no effect on whether a particular substance is a "pesticide" subject to FIFRA and its implementing regulations.

Whether a substance is a "pesticide chemical" under 21 U.S.C. § 321(q)(1) of the FFDCA, or a "food additive" under 21 U.S.C. § 321(s) of the FFDCA, has no effect on whether the substance is a "pesticide" subject to the regulatory coverage of FIFRA. The statutory provision defining the term "pesticide chemical" in the FFDCA expressly provides that "[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)(B). Thus, the plain language of the FFDCA statute makes it clear that the definition of the term "pesticide chemical" under the FFDCA is separate and distinct from the definition of "pesticide" for purposes of FIFRA.

The legislative history of FFDCA 21 U.S.C. §321(q)(1), further demonstrates that the definition of the term "pesticide chemical" under the FFDCA does not affect whether a particular substance is a "pesticide" under FIFRA. This definition was added to the FFDCA in amendments occasioned by the passage of the FQPA. As promulgated in 1996, the FQPA defined "pesticide chemical" as "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients." See 142 Cong. Rec. H. 8127, at 8134. However, this definition had the unintended consequence of extending U.S. EPA's tolerance-setting authority under Section 408 of the FFDCA (21 U.S.C. § 346a) over many substances formerly regulated by the FDA as "food additives" under Section 409 of the FFDCA (21 U.S.C. § 348). As a result of the wording in the FQPA, any antimicrobial "food additive" now fell within U.S. EPA's tolerance-setting authority under the FFDCA, simply because such "food additives" met the definition of "pesticide chemical" as set forth in the 1996 FQPA. To cure this problem, Congress passed the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA), which amended the definition of "pesticide chemical" in the FFDCA to incorporate the current language found in 21 U.S.C. § 321(q)(1)(A) and (B). See 144 Cong. Rec. H. 9898 (October 7, 1998). It is important to bear in mind that ARTCA only amended the FFDCA, and did not amend any portion of FIFRA; ARTCA only clarified U.S. EPA's and FDA's respective regulatory authorities and jurisdiction *under the FFDCA*. See 144 Cong Rec E 2197. That Congress did not intend to affect regulatory coverage of antimicrobials under FIFRA is evident from the final provision of 21 U.S.C. 321(q)(1): "With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act,

this clause [clause B (which creates the exclusion of "food additives" from the definition of "pesticide chemical")] does not exclude any substance from such definition.").

In statements made in connection with the passage of the definition of "pesticide chemical" under the FFDCA, Congress made clear that the statute would have no effect on FIFRA. For example, Representative Bliley, one of the authors of the legislation that created this definition of "pesticide chemical," made the following statement of Congress' intent that nothing in ARTCA would affect U.S. EPA's authority to regulate a substance as a pesticide for purposes of FIFRA:

> The technical correction made by H.R. 4679 does not remove any use of a substance from regulation as a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Thus, any use of an antimicrobial in the manufacture of packaging for both food and non-food applications that is a pesticidal use under FIFRA would, in addition to FDA review as a food additive, continue to be subject to pesticide registration under FIFRA.

144 Cong Rec E 2280, at 2281. Later, Representative Bliley stated "this amendment would affect the regulation of antimicrobial pesticides only under the FFDCA. EPA would continue to regulate antimicrobial pesticides under FIFRA, and EPA's authorities under that statute would not be changed." 144 Cong Rec E at 2281. Another member of Congress, Rep. Clayton, also expressed Congress' intent that this legislation would not affect regulatory coverage under FIFRA:

> This piece of legislation shifts the regulatory jurisdiction *for review and approval of petitions for use of antimicrobials in food contact applications*. It does not remove or amend pesticide regulations under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). *Antimicrobials will still be subject to registration under FIFRA* and standard FDA review for food additives.

144 Cong Rec E 2197 (October 15, 1998) (emphasis added). Therefore, it is clear that nothing in 21 U.S.C. §321(q)(1)(A) or (B) affects the applicability of FIFRA to

antimicrobial products. If such products meet the definition of "pesticide" set forth in Section 2(u) of FIFRA, 7 U.S.C. §136(u), or the implementing regulations at 40 C.F.R. §152.3 and 152.15, they fall within the regulatory coverage of FIFRA.[7]

For this reason, Respondent's fourth affirmative defense is insufficient to defeat liability as a matter of law, and should be stricken as irrelevant to the issues presented in this case.

C. Respondent's Fifth Affirmative Defense

Respondent's fifth affirmative defense states as follows:

> Behnke's products are "food additives" pursuant to 21 U.S.C. §321(s). Behnke's products are approved as lubricants with incidental food contact pursuant to 21 CFR 178.3570, a regulation promulgated pursuant to 21 U.S.C. §348(a). It is anticipated that such products will be subject to incidental food contact and ingestion. As such, Behnke's products are strictly regulated by the Food & Drug Administration pursuant to Section 409 of the Federal Food, Drug, and Cosmetic Act ("FFDCA").

The statutory citation provided by Respondent, 21 U.S.C. §321(s), is another section of the FFDCA. Like 21 U.S.C. 321(q)(1), it has no impact on the definition of the term "pesticide" under FIFRA. Respondent has provided nothing to show that a product's status as a "food additive" somehow exempts it from regulation as a pesticide under FIFRA. To the contrary, as revealed in the legislative history cited above in connection with the motion to strike Respondent's fourth affirmative defense, the fact that a product is a "food additive" will not operate to exempt that product from regulatory coverage under FIFRA, for Congress clearly envisioned that "food additives" could also be

[7] As with the FQPA, U.S. EPA was heavily involved in the process which resulted in passage of ARTCA. See 144 Cong Rec H 9898, at H 9899 (Rep. Bliley: "Mr. Speaker, when we passed FDA reform last year, the conference report acknowledged this problem and urged the FDA and EPA to work with Congress to develop a bill that would correct it. This is that bill. It was developed jointly with EPA and FDA, the affected industries, and the environmental community. I think they all should be commended for their cooperation and effort.")

pesticides regulated under FIFRA. As stated by Rep. Clayton in connection with the passage of ARTCA, "[a]ntimicrobials will still be subject to registration under FIFRA and standard FDA review for food additives." 144 Cong Rec E 2197. This expression of legislative intent demonstrates that Congress understood that a product could be subject to regulation as a pesticide under FIFRA and as a "food additive" under the FFDCA.

Furthermore, in amending the food additive regulations to provide for the safe use of different antimicrobial substances since the passage of ARTCA in 1998, the FDA has cautioned that, although these substances are regulated by the FDA as "food additives" under Section 409 of the FFDCA, and not by U.S. EPA as "pesticide chemicals" under Section 408 of the FFDCA, the intended use of these substances may subject them to regulation as pesticides under FIFRA. For example, in July of 1999, the FDA approved the use of an antimicrobial product as a food additive, but included the following cautionary note:

> The current approval under § 173.315 for the use of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid is to control the microbial growth in water that contacts fruits and vegetables that are not raw agricultural commodities (61 FR 46374, September 3, 1996). This intended technical effect is unchanged by this regulation. Under the Antimicrobial Regulation Technical Corrections Act (Pub. L. 105-324), such use in water that comes into contact with the food in the preparing, packing, or holding of the food for commercial purposes is subject to regulation by FDA as a food additive under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) and is not subject to regulation by the Environmental Protection Agency (EPA) as a pesticide chemical under section 408 of the act (21 U.S.C. 346a). *However, this intended use of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).* Therefore, manufacturers intending to use this food additive for this intended use should contact EPA to determine whether this use requires a pesticide registration under FIFRA.

CX 62, "Secondary Direct Food Additives Permitted in Food for Human Consumption," 64 Fed. Reg. 38563, at 38564 (July 19, 1999) (emphasis added).

Similarly, in another amendment to the food additive regulations that allowed the use of an antimicrobial product as a food additive, the FDA stated as follows:

> Under ARTCA, the use of acidified sodium chlorite solutions as an antimicrobial agent on RAC's in preparing, packing, or holding of such RAC's for commercial purposes, consistent with section 201(q)(1)(B)(i) of the act, and not otherwise included within the definition of "pesticide chemical" under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III), is subject to regulation by FDA as a food additive. *Although this use of acidified sodium chloride solutions as an antimicrobial agent on raw agricultural commodities is regulated under section 409 of the act (21 U.S.C. 348) as a food additive, the intended use may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).* Therefore, manufacturers intending to market acidified sodium chlorite solutions for such use should contact the EPA to determine whether this use requires a pesticide registration under FIFRA.

CX 63, "Secondary Direct Food Additives Permitted in Food for Human Consumption," 64 Fed. Reg. 49981 (September 15, 1999) (emphasis added). Finally, in September 2000, the FDA approved the use of an antimicrobial as a food additive, but also stated as follows:

> As a result of ARTCA, these petitioned antimicrobial uses are once again subject to regulation by FDA under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) and are not subject to regulation as pesticide chemicals under section 408 of the act (21 U.S.C. 346a). *Although these antimicrobial uses are regulated under section 409 of the act as food additives, nevertheless, the intended uses may be subject to regu-lation as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).* Therefore, persons intending to market these food additives for such antimicrobial uses should contact the EPA to determine whether such uses require a pesticide registration under FIFRA.

CX 64, 65 Fed. Reg. 6889, at 6890 (February 11, 2000) (emphasis added).

These examples demonstrate that the FDA, the governmental agency principally responsible for implementing the FFDCA, has historically viewed the subject of regulatory jurisdiction under the FFDCA, as amended by the FQPA and ARTCA, as separate and distinct from regulatory jurisdiction under FIFRA. This further illustrates the error of Respondent's fifth affirmative defense: the FDA, the regulatory body responsible for interpreting and enforcing Section 409 of the FFDCA and for promulgating the "food additive" regulations, adheres to the plain reading of the statute, and does not interpret it in the strained manner advanced by Respondent's Affirmative Defenses 4 and 5.

D. Respondent's Sixth Affirmative Defense

Respondent's sixth defense states as follows:

> 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. 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.

Respondent appears to be arguing that Behnke's products fall with the "Treated articles or substances" exemption set forth in FIFRA's implementing regulations, at 40 C.F.R. § 152.25(a). However, this argument fails under the plain language of the exemption. "Treated articles or substances" are considered to be "of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified." However, in order to qualify for the "treated articles or substances" exemption, an article or substance must satisfy the following 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) (emphasis added). Significantly, the article or substance at issue must contain, or must have been treated with, a pesticide that has been registered under FIFRA for use in protecting the article or substance. In the instant matter, Behnke has not provided any evidence that the lubricant products at issue in this case either contain or have been treated with a pesticide that has been registered under FIFRA for use as an antimicrobial designed to protect the lubricants. Therefore, Behnke cannot avail itself of the "treated articles or substances" exemption; this affirmative defense is also legally insufficient and should be stricken.

IV. Motion for Discovery

Complainant also moves for discovery in connection with Respondent's Affirmative Defenses 1, 2 and 7. Furthermore, should the Court deny Complainant's motion to strike (set forth above), Complainant moves in the alternative for discovery in connection with Respondent's Affirmative Defenses 5 and 6.

The information requested in this motion for discovery is actually required for Respondent to support its affirmative defenses. Section 22.15(b) of the Consolidated Rules of Practice states that "the answer shall also state: the circumstances or arguments which constitute the grounds of any defense..." 40 C.F.R. § 22.15(b). The "Affirmative Defenses" set forth in Respondent's answer merely state legal conclusions, and are largely unsupported by facts or reasoning. Under the applicable rules of practice, Respondent is required to state the "circumstances or arguments" which support the grounds of its affirmative defenses in its answer to the complaint, yet only minimal

information regarding Respondent's circumstances or arguments has been provided in either its answer or its prehearing exchange.

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

In Affirmative Defenses 1, 2, 6 and 7, Respondent appears to rely on certain exemptions or exceptions to FIFRA regulatory coverage set forth in the FIFRA statute or its implementing regulations. Affirmative Defenses 1 and 2 appear to argue that Behnke's lubricant products meet an exception to the definition of "pesticide" found in Section 2(u) of FIFRA, 7 U.S.C. § 136(u), and Affirmative Defense 7 is based on the contention that the microorganisms targeted by the claims associated with Behnke's products fall within an exception to the definition of "pest" found in 40 C.F.R. § 152.5(d). Affirmative Defense 6 appears to invoke the "treated articles or substances"

exemption in 40 C.F.R. § 152.25(a). Therefore, Respondent bears the burden of production and the burden of persuasion to substantiate these affirmative defenses.

To avoid an accelerated decision rejecting these affirmative defenses, Respondent must produce substantial evidence to support these affirmative defenses. Respondent has failed to produce any actual evidence to substantiate its affirmative defenses, and the failure to produce such evidence should result in an accelerated decision against Respondent on these defenses. As the Chief Administrative Law Judge has observed: "[f]or the EPA to prevail on a motion for accelerated decision on an affirmative defense, as to which Respondent ultimately bears such burdens, EPA initially must show that there is an absence of evidence in the record for the affirmative defense." *In the Matter of Minnesota Metal Finishing*, Docket No. RCRA-05-2005-0013, 2007 EPA ALJ LEXIS 1, at 8 (Order on Complainant's Motion for Accelerated Decision, January 9, 2007), *citing Rogers Corporation v. EPA*, 275 F.3d 1096, 1103 (D.C. Cir. 2002). If Complainant makes this requisite showing, "then Respondent 'as the non-movant bearing the ultimate burden of persuasion on its affirmative defense, must meet its countervailing burden of production by identifying 'specific facts' from which a reasonable factfinder could find in its favor by a preponderance of the evidence.'" *Id., citing Rogers Corporation.* Respondent cannot "meet its burden of production by resting on mere allegations, assertions, or conclusions of evidence." *Minnesota Metal Finishing*, 2007 EPA ALJ LEXIS 1, at 8-9, *citing BWX Technologies, Inc.*, 9 E.A.D. 61, 75 (EAB 2000).

Therefore, as part of its prehearing exchange submittal, Respondent must provide substantial evidence in support of its affirmative defenses. As the Chief Judge also noted, in the context of a motion for an accelerated decision on an affirmative defense, "[w]hile

submissions [of information supporting an affirmative defense] must be viewed in [a] light most favorable to the nonmovant, including one who bears the burden of persuasion on the issue, and such evidence is to be taken as true, Respondent must provide 'more than a scintilla of evidence on a disputed factual issue to show [its] entitlement to a trial or evidentiary hearing; the evidence must be substantial and probative in light of the appropriate evidentiary standard of the case.'" *Minnesota Metal Finishing*, 2007 EPA ALJ LEXIS 1, at 9, *citing BWX Technologies, Inc.*, 9 E.A.D. at 76.

In its June 21, 2007, *Notice of Complainant's Request for Voluntary Production of Information*, Complainant requested that Respondent voluntarily produce the information necessary to support its defenses, but no responsive information has been produced to date. Therefore, Complainant hereby moves for discovery of the specific information identified in its June 21, 2007, *Notice of Complainant's Request for Voluntary Production of Information*, as well as additional information described below. Should Respondent fail to produce the information identified below, Behnke's affirmative defenses should be rejected as unsupported.

A. Standard for Granting a Motion for Other Discovery

In proceedings subject to the Consolidated Rules of Practice, motions for additional discovery are governed by Section 22.19(e) of the Consolidated Rules, 40 C.F.R. § 22.19(e). This rule provides that, after the prehearing exchange has taken place, other discovery may be ordered only if such discovery: (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. As explained in Section V, below, this motion for other discovery satisfies each of these elements.

V. Factors for "Other Discovery"

A. The Prehearing Exchange Has Taken Place

Under the Consolidated Rules, a Party may request "other discovery" only after the prehearing information exchange ordered by the Presiding Administrative Law Judge has been completed. 40 C.F.R. § 22.19(e). The prehearing information exchanges in this case concluded with the filing and service of Complainant's Second Supplemental Prehearing Exchange on January 9, 2007. Therefore, Complainant may appropriately file this motion for additional discovery.

B. The Motion for "Other Discovery" Will Neither Unreasonably Delay the Proceeding Nor Unreasonably Burden the Non-moving Party

The Presiding Administrative Law Judge may grant a motion for "other discovery" only if doing so will neither unreasonably delay the proceeding nor unreasonably burden the non-moving party. Granting the motion for discovery in the instant matter will not unreasonably delay the proceeding, as the hearing in this matter has only recently been scheduled, and will not commence until March 31, 2008, more than two months from today's date. Nor will granting Complainant's discovery motion unreasonably burden Respondent. All of the documents and other information requested herein are within Respondent's possession (if they exist at all), and are clearly relevant and necessary to ascertain the viability of defenses asserted by Respondent (as explained in greater detail in subsection D, below).

C. The Motion for "Other Discovery" Seeks Information that Is Most Reasonably Obtained from the Non-moving Party, and Which the Non-moving Party Has Refused to Provide Voluntarily

The Presiding Officer Administrative Law Judge may grant a motion for "other discovery" only if the Judge determines that the motion seeks information which is most reasonably obtained from the non-moving party and which the non-moving party has refused to provide voluntarily. The Complainant seeks information pertaining to Respondent's affirmative defenses, information which is solely in the possession of the Respondent. The discovery motion seeks information concerning Respondent's own products, and Behnke's communications with and submittals to regulatory agencies. This information is undeniably within Respondent's possession, and Complainant cannot obtain the information requested in this motion from any source other than Respondent. Therefore, the information sought by this motion is most reasonably obtained from Respondent.

In addition, Respondent has refused to provide the information sought by this motion. Complainant requested much of the information that is the subject of this motion in its June 21, 2007, request for voluntary production of information. Complainant requested all such information in its Rebuttal Prehearing Exchange, which was filed and served on Respondent on November 15, 2007, but Respondent has not provided any responsive information. Respondent has therefore refused to voluntarily provide the requested information.

D. The Motion for "Other Discovery" Seeks Information that Has Significant Probative Value On a Disputed Issue of Material Fact

With respect to those affirmative defenses which Complainant has moved to strike (specifically, Affirmative Defenses 5 and 6)[8], whether the information sought with respect to those particular defenses has "significant probative value on a disputed issue of material fact" depends on this Court's ruling with respect to Complainant's motion to strike. Should the Court grant Complainant's motion to strike these defenses, the alternative motion for discovery of information relating to those defenses will become moot.

As explained above, Complainant maintains that, as a matter of law, Affirmative Defenses 5 and 6 are insufficient to defeat liability. To date, Respondent has only asserted these arguments as defenses against liability.

1. Discovery of Information Concerning Affirmative Defenses 1, 2 and 7

Respondent's first defense states that "Behnke's products are not 'pesticides' within the meaning of 7 U.S.C. §136(u)," and its second defense asserts that "Behnke's products do not contain a 'pesticide' as defined by 7 U.S.C. §136(u)." Behnke asserts that the lubricants in question are not pesticides, do not contain pesticides, nor are they intended for a pesticidal purpose, and that the microorganisms targeted by these products are not "pests." However, Respondent's conclusory statements are refuted by a plain reading of the FIFRA statute and its implementing regulations that define the term "pesticide." Section 2(u) of FIFRA defines the term "pesticide" as "(1) any substance or

[8] Complainant is not seeking discovery of the information previously requested on June 21, 2007, in connection with Respondent's Affirmative Defenses 3 and 4. Complainant believes that these two defenses are not only insufficient as a matter of law as defenses to liability, but also completely irrelevant to any other issue presented in this case. Therefore, no information relating to these defenses could have any relevance.

mixture of substances intended for preventing, destroying, or mitigating any pests," and the term "pest" is defined under Section 2(t) of FIFRA as, *inter alia*, any "virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator [of U.S. EPA] declares to be a pest under section 136w(c)(1) [of FIFRA]." 7 U.S.C. §§ 136(u) and 136(t). Pursuant to Section 136w(c)(1) of FIFRA, U.S. EPA promulgated regulations under which "[a]n organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is[, inter alia,]: (d) 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 ..." 40 C.F.R. § 152.5(d). *See In re: William E. Comley, Inc. & Bleach Tek, Inc.*, 11 E.A.D. 247, at 249 (EAB 2004). The regulations promulgated to implement FIFRA define "pesticide" as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." 40 C.F.R. § 152.3. The regulation at 40 C.F.R. § 152.15 provides that "[a] pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest," and further provides that "[a] substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if[, *inter alia*,] "the person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) ... that the substance (either by itself or in combination with any other substance) can or should be used as a pesticide." 40 C.F.R. § 152.15(a)(1). *See In re: The Bullen Companies*, 9 E.A.D. 620, at 622-23 (EAB 2001). Respondent admits that Behnke made various antimicrobial claims described in the Complaint. *See, e.g.,*

Complaint and Answer, §§ 18, 20, 31, 41, 55 and 65. Each of these claims is clearly a "pesticidal claim" within the meaning of 40 C.F.R. § 152.15(a)(1). In addition, the microorganisms identified in Behnke's antimicrobial claims are all considered "pests" within the meaning of FIFRA. *See Kenepp v. American Edwards Laboratories*, 859 F.Supp. 809, at 816, n. 4 (E.D. PA 1994) (rejecting argument that, because antimicrobial product targeted Human Immunodeficiency Virus, it was not a pesticide under FIFRA; court held that "[t]he defendants' products are designed in part to kill Human Immunodeficiency Virus (Type 1) on hospital instruments, and are not for use 'on or in living man.' Accordingly, the court finds that the defendants' products are 'pesticides' within the meaning of FIFRA."); *and In the Matter of Super Chem Corporation*, Dkt. No. FIFRA-9-2000-0021, 2002 EPA ALJ LEXIS 25, Slip. Op. at 11 (April 24, 2002) (ALJ noting that "[t]he record evidence in this case overwhelmingly shows that [Respondent's product] is [a pesticide," and noting fact that product held itself out to be a pesticide because its label stated that product was a "Disinfectant-Sanitizer," that it was "to be used for disinfection in hospitals, nursing homes and schools," and that it was "effective against the bacteria Escherichia coli"). Therefore, on the basis of Respondent's Answer and its current prehearing exchange, Behnke has failed to provide any evidence to substantiate its argument that the products at issue are not "pesticides" within the meaning of FIFRA, nor has Respondent supported its argument that microorganisms such as Salmonella, Listeria and E-coli are not "pests."

With respect to Respondent's Affirmative Defenses 1, 2 and 7, Complainant seeks information necessary to determine the facts on which Respondent bases its arguments (1) that Behnke's lubricant products are not "pesticides," and do not contain a

"pesticide," as defined under Section 2(u) of FIFRA, 7 U.S.C. § 136(u); and (2) that the microorganisms targeted by Behnke's antimicrobial (pesticidal) claims are not "pests" within the meaning of Section 2(t) of FIFRA, 7 U.S.C. § 136(t). Behnke has produced no evidence or information in its prehearing exchange that provide a factual basis for either of these arguments. Therefore, Complainant requests that this Court order Respondent to produce the following information with respect to Behnke's Affirmative Defenses 1, 2 and 7:

a. Any and 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, or concerning any lubricants containing Micronox, including but not limited to the following agencies: the United States Food and Drug Administration (FDA); the United States Department of Health and Human Services (DHHS); and the U.S. EPA, Antimicrobial Division in the office of Pesticides Program (OPP).

This information is relevant to ascertain whether or how Behnke described the Micronox technology and its antimicrobial functions and qualities to regulatory agencies. This will help determine whether, as Behnke appears to suggest, the intended use of Behnke's products targeted only microorganisms exempt from the definition of "pest" set forth in 40 C.F.R. § 152.5(d).

In addition, Complainant previously noted that "the chemical components of the lubricants may become relevant to determine if there are active ingredients that are known pesticides or have known pesticidal properties in the lubricants." *See Notice of Complainant's Request for Voluntary Production of Information*, pp. 6-7. Therefore, Complainant requests that this Court order Respondent to produce the following information: "a list of the chemical components of each of the following 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, by chemical name and by C.A.S. Number." *See Notice of Complainant's Request for Voluntary Production of Information*, p. 7. Should Respondent wish to have this information protected as trade secrets or confidential business information, appropriate safeguards against unauthorized disclosure will be implemented in accordance with 40 C.F.R. Part 2.

Complainant further requests that Respondent be ordered to provide all documents that specifically describe the intended uses of Behnke's products (including but not limited to all correspondence with customers, and all advertising and technical literature). This information is relevant to determine whether Behnke's products contain active ingredients which by their presence alone make the products pesticides under FIFRA. The requested information is also relevant to determine whether the antimicrobial functions of Behnke's products, or the intended uses of these products, in fact target only microorganisms that are exempt from the definition of "pest" under FIFRA, as Behnke alleges in Affirmative Defense 7.

2. Discovery of Information Concerning Affirmative Defenses 5 and 6

Complainant has moved to strike these Affirmative Defenses on the grounds of legal insufficiency. Obviously, if this Court agrees with Complainant and strikes these defenses, the information pertaining to these defenses requested in Complainant's alternative motion for discovery will not have probative value, and Complainant's discovery motion will become moot.

However, if this Court decides not to strike Respondent's Affirmative Defenses 5 and 6, the information sought by this motion will have significant probative value in evaluating the legitimacy of Respondent's arguments.

Affirmative Defense No. 5

In connection with Affirmative Defense 5, Respondent asserts that its products are "food additives" that are anticipated to have incidental contact with food, and that will be subject to ingestion. *See Answer*, p. 28. Respondent claims (without substantiation or explanation) that its products are "strictly regulated by the Food & Drug Administration pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA)." *Id.*

As explained above, this defense is insufficient as a matter of law to defeat liability under FIFRA. However, should the Court disagree, or to the extent that the Court believes that any of Respondent's assertions with respect to this defense are relevant to the issue of penalties (and Respondent timely moves to amend its Answer to incorporate these arguments as defenses to the penalty amount), Complainant requests that Respondent be ordered to produce the following information:

> a. A detailed explanation of how "Behnke's products are strictly regulated by the Food & Drug Administration," and true, accurate and complete copies of all documents that substantiate such "strict regulation," including but not limited to the following types of documents: all correspondence between Behnke and the FDA concerning Behnke's products or the Micronox technology; all documents reflecting laboratory tests or other data which demonstrate the efficacy of Behnke's products as antimicrobials; all documents reflecting laboratory tests or other data which demonstrate the safety of Behnke's products; and all documents submitted by Behnke to the FDA with respect to its products or the Micronox technology. If documents responsive to this request do not exist, Respondent should be required to state affirmatively that no such documents exist.
>
> b. 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 regarding 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 that were submitted to the Food and Drug Administration or the Dept. of Health and Human Services (DHHS) pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).[9]
c. True, accurate and complete copies of all documents containing the following information:

i. The identity of the lubricant/food contact substance.

ii. The intended use of the lubricant/food contact substance.

iii. Behnke's determination that the intended use of the lubricant/food contact substance was safe in accordance with Section 409(c)(3)(A) of the FFDCA.

iv. All supporting information that forms the basis of such a determination and all information required to be submitted by the applicable regulations implemented by the FFDCA.

v. If such notifications do not exist, an explanation of its absence for each lubricant listed above, and all supporting documentation.

The information identified above is relevant to ascertain the accuracy of Respondent's assertions that its products were "approved as lubricants with incidental food contact," and that such products are "strictly regulated" by the FDA. *See Answer*, p. 28. The requested information will help to clarify the extent to which there is true, active regulatory oversight of these products by the FDA; furthermore, this information will help determine whether or not such FDA regulatory oversight in any way satisfies the environmental or public health concerns that would have been addressed had Behnke applied for FIFRA registration of these products.

Also in connection with affirmative defense 5, Complainant requests that the Court order Respondent to provide the following information:

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[9] This information was requested in Complainant's June 21, 2007, *Notice of Complainant's Request for Voluntary Production of Information*, p. 3.

a. Pursuant to 21 C.F.R. Section 178.3570, indicate how Behnke's Micronox 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, can be safely used on machinery that is used for packing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

b. Specify whether each product can be used safely because the lubricants are prepared from one or more of the following substances:

i. The substances are generally recognized as safe for use in food. Provide supporting documentation.
ii. The substances are used in accordance with the provisions of a prior sanction or approval. Provide supporting documentation.
iii. The substances are identified in 21 C.F.R. Section 178.3570(a)(3). Provide supporting documentation.

c. Identify the specific substances in each lubricant that fall in each category listed in b.i – iii, above.

All of this information is relevant to ascertaining whether the products in question were regulated by the FDA in a manner that could address any of the underlying human health and environmental concerns that would have been served by regulatory scrutiny of the products under FIFRA.

Also in connection with Affirmative Defense 5, Complainant requests that the Court order Respondent to provide the following information:

True, accurate and complete copies of all documentation and communication between Behnke and NSF International regarding any Behnke lubricants containing Micronox, including 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. Responsive documents will include, but are not limited to, the following:

a. NSF registration applications and responses for the above-named lubricants.
b. Any communication between Behnke and NSF regarding label changes that were needed for each of the above-named lubricants.
c. Any formulation data that was submitted to NSF for each of the above-named lubricants for the purpose of registration.

d. Any labels that were submitted to NSF for the above-named lubricants for the purpose of registration.

e. Submissions of intended use classification and category code for each of the lubricants.

f. Any information relating to the listing of these lubricants in NSF's White Book listing.

g. Registration letters for each of the above-named lubricants.

h. All labels submitted to NSF on or after January 1, 2002 relating to the above-named lubricants.

i. Copies of all advertising and print media on Behnke's website that resulted after the registration of these lubricants by NSF.

j. Any communication between Behnke and NSF in 2002 through 2005 regarding language changes on the labels of the above-named lubricants.

k. Any communication between Behnke and NSF that relates to NSF requesting that Behnke seek approval from the U.S. EPA to register Micronox lubricants and to label and identify the Micronox lubricants as pesticides.

l. Any court documents and communications between Behke and NSF as a result of the declaratory judgement filed by Behnke against NSF relating to the registration of Micronox lubricants such as 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, Case No. 2:06-cv-00353-RTR, Waukesha County Case Co. 06CV134.

In addition, as Complainant pointed out in its June 21, 2007, *Notice of Complainant's Request for Voluntary Production of Information*, the United States Department of Agriculture (USDA) created the original food-grade designations H1, H2, and H3, by which the USDA would approve a food-grade lubricant and register such lubricant within one of these categories based on the list of ingredients. Since September 30, 1998, the USDA ceased issuing registrations of food-grade lubricants, and NSF International (NSF) evolved to take over the responsibility for issuing registrations of food-grade lubricants. See http://www.nsf.org/business/newsroom/regworld01-1/rw_page4.html.

Upon information and belief, Behnke has registered the lubricants in question with NSF.[10] Therefore, Complainant also requests that the Court order the production of the following information in connection with NSF evaluation requirements:

> True, accurate and complete copies of all documentation submitted by or on behalf of Behnke to NSF so that NSF could complete its evaluation requirements for 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. Such documents should include, but not be limited to, the following:
>
> m. Product name;
> n. A qualitative and quantitative (percentage of weight) identification of all constituents;
> o. The Chemical Abstract Service (CAS) number, if applicable;
> p. The chemical ingredient names based on the International Union of Pure and Applied Chemistry (UPAC) rules;
> q. Suppliers or sources of each ingredient;
> r. Prior product regulatory approval from any state or country regulatory authority;
> s. Appropriate FDA regulatory reference for each ingredient in 21 CFR Sections 178.3570, 172.860 and 172.878;
> t. A copy of the product label submitted to NSF along with the registration application; and
> u. Any notifications, if any, submitted to NSF as a result of changes to the registered formulations.

See Notice of Complainant's Request for Voluntary Production of Information, p. 6. The information requested above, is relevant to determine exactly what information Behnke provided in connection with obtaining any "approvals" for its products from the NSF, which is the organization currently responsible for registrations of food-grade lubricants. This information will be necessary to evaluate Behnke's assertions with respect to Affirmative Defense 5. To the extent that the NSF certification process referred to in Respondent's Prehearing Exchange (at p. 3) provides any regulatory oversight over

[10] Behnke has identified a witness, Ms. Patty Riek, who is apparently prepared to testify about "certification of respondent's products as NSF H-1 food grade lubricants" and "the certification process of the six products identified in the EPA's complaint." *See Respondent's Initial Prehearing Exchange*, at 2-3.

Respondent's lubricant products, such information will help determine the nature and extent of any such oversight, and will assist the Court in evaluating Respondent's claim that its products are "strictly regulated by the Food & Drug Administration," and will help the Court assess the extent to which such FDA or NSF oversight fulfills any of the purposes and goals of FIFRA that would have been served had Behnke applied for FIFRA registration of its products or the Micronox technology. The information requested is also necessary to prepare for the examination of Respondent's witness, Ms. Riek.

Affirmative Defense No. 6

In connection with Affirmative Defense 6 (in which Respondent asserted that the lubricants in question "are formulated to resist internal degradation from contaminants found in food processing environments."), Complainant requests that the Court order Respondent to provide the following information:

a. Clarify how 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, are formulated to resist internal degradation from contaminants found in food processing environments.

b. Specifically identify the contaminants that Behnke is referring to in its affirmative defense number 6. If such contaminants are microorganisms, explain how Behke complied with the treated article exemption pursuant 40 CFR Section 152.25.

c. Identify the antimicrobial additive that is in each of the following 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, by chemical name. C.A.S. Number and EPA Registration number.

The information requested is relevant to evaluate whether Behnke can avail itself of the "treated articles and substances" exemption (assuming that the Court allows Behnke to continue to assert this defense).

VI. Request for Additional Documents and Information

Complainant respectfully requests that this Court order Respondent to produce the following information in a Supplemental Prehearing Exchange no later than March 3, 2008:

1. Complainant requests that the Court order Respondent to provide context for RX 54 ("Behnke Publication regarding food grade lubricant certification"), including an explanation as to what the document is, who created it, when it was created, why it was created, to whom and when it was distributed, and why it was distributed. Such information is necessary to determine how RX 54 relates to any of Behnke's defenses.

2. Complainant requests that the Court order Respondent to supplement its Prehearing Exchange to affirmatively state 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, as required by the June 27, 2007, Prehearing Order.

3. Complainant requests that the Court order Respondent to either produce complete and reliable evidence of its actual gross sales, or expressly waive 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. § 136l(a)(4).

4. Respondent has identified an expert witness, Shaun Beauchamp, from a company called Xact Fluid Solutions. According to the website of this company, Xact appears to

be an operating division of Behnke. Complainant requests that the Court order Respondent to provide clarification on the relationship between Xact Fluid Solutions and Behnke. Specifically, Respondent should be directed to indicate whether Xact Fluid Solutions is a subsidiary or an operating division of Behnke, and what services or products are provided by Xact Fluid Solutions on behalf of Behnke. Such information will assist the Court in evaluating the testimony of the Xact witness.

5. Complainant requests that the Court order Respondent to provide additional detail in its narrative summaries of the expected testimony of its witnesses. Respondent's narrative summaries are deficient, and fail to meet the standards established by the Consolidated Rules of Practice and decisions of Administrative Law Judges interpreting those rules. Section 22.19(a)(2) of the Consolidated Rules of Practice provides that "[e]ach party's prehearing information exchange shall contain: (i) The names of any expert or other witnesses it intends to call at the hearing, together with a brief narrative summary of their expected testimony . . ." As this Court held in *In the Matter of Gerald Strubinger and Gregory Strubinger*, Dkt. No. CWA-3-2001-001, 2002 EPA ALJ LEXIS 44 (July 12, 2002), a summary of a witness's anticipated testimony must be sufficiently detailed to provide the opposing party an adequate opportunity to prepare for hearing. In that case, Respondent had provided in its prehearing exchange summaries of witness testimony such as "intended witnesses Joseph Lesisko, Mary Louise Lesisko, Victor Izzo, and Carolyn Izzo will present testimony as to the storm water runoff that passes through their backyards and that of Respondent's property," "Ed Gula of the Jim Thorpe Borough is to testify as to the testing of fecal coliform," "William Kee of Cowan and Associates ... will testify as to his work for the Borough of Jim Thorpe and its impact on the site in

question" and "Ronald Tirpak, P.E. will testify as to his work and knowledge of the subject and surrounding properties." *Strubinger*, Dkt. No. CWA-3-2001-001, Slip Op., at 2-3. Complainant filed a motion "to compel Respondent to more fully identify certain witnesses and to describe the expected testimony of these witnesses with greater specificity or in the alternative, to preclude Respondent from presenting the testimony of such witnesses at hearing." Slip Op., at 2. This Court agreed that such narrative summaries were deficient:

> Complainant's argument that Respondent should provide additional and more specific information concerning the 22 intended witnesses identified above and their expected testimony is persuasive. See 40 C.F.R. §§ 22.19(a); 22.22(a). Respondent's narrative summaries of the expected testimony of these 22 witnesses contained in its prehearing exchange do not afford Complainant an adequate opportunity to prepare for hearing. The additional information concerning these witnesses requested by Complainant would not be unduly burdensome for Respondent to provide.

Slip Op., at 4. Hence, narrative summaries of the expected testimony of a party's witnesses must contain more than general references to subjects about which the witness shall testify. *See also In the Matter of Henry Velleman, Individually, and d/b/a Progressive Poletown Properties*, Docket No. 5-CAA-97-008, 1998 EPA ALJ LEXIS 27 (March 18, 1998).

In the instant matter, Behnke's narrative summaries of the expected testimony of several of its witnesses provide no more detail than did the summaries of witness testimony at issue in the *Strubinger* case. Complainant believes that these narrative descriptions are deficient, as the descriptions are so vague and terse that it is unclear what the witnesses will be testifying about, or how such testimony relates to any issues raised by the Complaint or Answer. As currently described, the testimony of each of these witnesses does not appear to be remotely relevant to any issues relating to either liability

or the amount of the penalty. Therefore, Complainant requests that the Court order Respondent to provide additional details on the proposed testimony of each of the following witnesses, as described below.

Mr. Carter Anderson. Respondent has identified this witness to testify about, *inter alia*, "the application of respondent's food grade products in the field and, in particular, the six products specifically at issue in this matter." *Respondent's Initial Prehearing Exchange*, at 2. However, no information has been provided as to how the products are applied, such as frequency of application, location of application, the equipment to which each product is applied, and instructions as to how the product is to be applied. This witness is also supposed to testify "that, as a marketing professional, he is keenly aware of the customer's needs and wants from respondent's products and their motives in purchasing these products in particular." *Respondent's Initial Prehearing Exchange*, at 2. However, Respondent fails to identify these supposed "customer's needs and wants" and "motives," nor has Respondent provided any information that would indicate how these needs, wants and motives relate to any of the issues presented by the Complaint and Answer. In addition, the customers' identities have not been provided. Complainant therefore requests that the Court order Respondent to provide the missing information identified in this paragraph.

Ms. Patty Riek. This witness is to testify, inter alia, about "the NSF certification process in general" and "the certification process of the six products identified in the EPA's complaint." *Respondent's Initial Prehearing Exchange*, at 3. However, no NSF certification materials or documents relating to "the certification process of the six products identified in the EPA's complaint" have been provided. No information about

this certification process has been provided in Respondent's Prehearing Exchange. Respondent has only identified a very general subject, without summarizing Ms. Riek's actual testimony. There is no information on which Complainant or the Court can discern whether or not Ms. Riek's testimony will have any relevance or probative value. In order for Complainant to adequately prepare for hearing, Respondent must be ordered to produce the missing information identified herein. Complainant respectfully requests the Court to issue such an order for additional details on Ms. Riek's testimony, and for all documents shared between Behnke and NSF or the USDA with respect to certification of the products at issue.

Mr. Mike Keller. This witness is identified as a salesperson who may testify about, *inter alia*, "his familiarity with the specific application and uses of the products identified in the EPA's complaint by the customers identified therein. However, there is no information on what these "specific application[s] and uses" are, nor are there any details on how, where, on what, and how often each product is applied by each customer. In addition, there is no explanation of the basis for Mr. Keller's alleged knowledge of such matters. Complainant respectfully requests the Court to issue such an order for these additional details, and for all documents shared between Behnke and each of the customers identified in the Complaint with respect to the application and use of the products at issue.

Mr. Larry Bradstreet, Mr. Mike Pike, and Mr. Eddie Chancellor. These witnesses are all employees of Tyson Foods. All three are to testify about "the actual and intended use and application of respondent's products by Tyson Foods." *See Respondent's Initial Prehearing Exchange*, at 4-5, and 7. However, there is no

description of such intended and actual uses. If Respondent is allowed to call this witness and elicit such testimony, Complainant needs considerably more detail on what the actual uses of the products are at Tyson Foods, including how and to what equipment the products are applied. Complainant also must have access to all documents shared between Tyson and Behnke with respect to the intended uses and actual uses of such products. Complainant requests that this Court order Respondent to produce true, accurate and complete copies of all such documents.

Mr. Pike is also expected to "offer evidence of how the properties described in respondent's literature directly impacts [sic] the quality and safety of the processed foods produced by Tyson Foods and, ultimately, the health and safety of its consumers." *Respondent's Initial Prehearing Exchange*, at 5. However, there is no information as to which properties are being discussed, or how such properties affect "the quality and safety of the processed foods produced by Tyson Foods and, ultimately, the health and safety of its consumers." *Respondent's Initial Prehearing Exchange*, at 5. Complainant is entitled to have such information, as well as true, accurate and complete copies of all documents shared between Tyson and Behnke in which such properties and their impacts are discussed. Complainant requests that this Court order Respondent to provide the information identified herein, and order Respondent to produce true, accurate and complete copies of all such documents.

Mr. Shaun Beauchamp. This witness is also identified as an expert, "an engineer employed by respondent who designs equipment for the physical application of the products identified in the EPA's complaint to lubricant points in the customers' plants," and who "is knowledgeable about specific applications within the plants of some

of the customers identified in the EPA's complaint." *Respondent's Initial Prehearing Exchange*, at 8. However, Respondent fails to provide any information about the details of these applications, and also fails to identify which customers Mr. Beauchamp has knowledge about with respect to the application of Behnke's products in those facilities.

Mr. Beauchamp is also supposed to testify "that, in their intended use the six products ... may reasonably be expected to result, directly or indirectly, in its [sic] becoming a component or otherwise affecting the characteristics of food." *Respondent's Initial Prehearing Exchange*, at 8. However, no information is provided as to how this occurs, nor has Respondent offered any information that might help ascertain whether and how this testimony is relevant to the issues presented in this case. Finally, no documentation is provided as to the design or engineering principles of the lubricating equipment referred to in Respondent's narrative summary.

Complainant requests that the Court order Respondent to provide greater detail in its narrative summary of Mr. Beauchamp's testimony, including details on what specific equipment he has designed, and for which customers; how this equipment applies Behnke's lubricant products, and to what areas and particular equipment of each customers's plant; and how the products can be reasonably be expected to result, directly or indirectly, in its [sic] becoming a component or otherwise affecting the characteristics of food." Complainant also respectfully requests this Court to order Respondent to produce true, accurate and complete copies of all the specifications and design plans for the equipment that Mr. Beauchamp may testify about, all documents that describe each of the six customer's needs and uses of product, and all documents that discuss how any of

the products may "reasonably be expected to result, directly or indirectly, in its [sic] becoming a component or otherwise affecting the characteristics of food."

Mr. Troy Paquette. Respondent identifies an expert witness, Troy Paquette, who will testify to "background information regarding customer demands and requirements that lead [sic] to the investment in research and development of this technology including testing that demonstrated the antimicrobial properties of the additives." *See Respondent's Prehearing Exchange*, at 7-8. Complainant does not believe that this proposed testimony, as described, is relevant to any issues relating to either liability or the amount of the penalty. However, in the event that such testimony is deemed relevant by this Court, Complainant requests that the Court order Respondent to produce true, accurate and complete copies of all of the data and reports generated with respect to the "testing that demonstrated the antimicrobial properties of the additives" in the Behnke products at issue in the Complaint, and all documents relating to the test methods used and laboratory practices employed. Such material should include, but not be limited to, all laboratory analytical reports, all raw data, all test methods used, all Quality Assurance and Quality Control plans followed by the laboratory, all standard operating procedures followed by the laboratory, and all chain-of-custody forms. Such information is necessary in order to evaluate the reliability of such claimed testing of the antimicrobial properties of Behnke's products.

Mr. Eric Peter. Respondent's description of the proposed testimony of Mr. Eric Peter includes testimony about "the history and development of food grade lubricants for use within food and beverage processing plants," "the market demands for such products that were generated by U.S. Department of Agriculture regulations," "the needs and

concerns in the food and beverage industry that motivated the investment of time and resources to the development and implementation of [Behnke's] products and technology, namely, food and consumer safety." *See Respondent's Prehearing Exchange*, at 1-2. First, this description fails to reveal how any of this testimony could be relevant to Respondent's liability for the sale/distribution of unregistered pesticides under FIFRA; nor does Respondent's narrative summary of this testimony indicate how it could be pertinent to any other issue raised in the Complaint or Answer. Complainant requests that this Court order Respondent to provide more detail in its narrative description of Mr. Peter's testimony, detail sufficient to show how this proposed testimony relates to any of the issues raised either in the Complaint or Respondent's Answer.

In addition, these areas of testimony encompass subjects of expert testimony, such as "the history and development of food grade lubricants for use within food and beverage processing plants," and "the market demands for such products that were generated by U.S. Department of Agriculture regulations." The narrative description of Mr. Peters' testimony fails to indicate how he knows about these subjects, nor does the vague description identify the actual nature of this witness' testimony. Therefore, Complainant requests this Court to order Respondent to produce Mr. Peter's curriculum vitae or resume, and to more fully describe what he will testify to at the hearing in this matter.

Mr. Charles Goodale. This is another expert witness who is expected to testify about the use of Behnke's products and "that, in their intended use the six products ... may reasonably be expected to result, directly or indirectly, in its [sic] becoming a component or otherwise affecting the characteristics of food." *Respondent's Initial*

Prehearing Exchange, at 8. Complainant respectfully requests that the Court order Respondent to produce all documents authored or reviewed by Mr. Goodale which describe or discuss how "in their intended use the six products ... may reasonably be expected to result, directly or indirectly, in its [sic] becoming a component or otherwise affecting the characteristics of food." Complainant also requests that the Court order Respondent to describe in sufficient detail the basis for Mr. Goodale's knowledge of Behnke's products and their application and use at Anheuser-Busch's bottling process, such as whether Mr. Goodale actually applied Behnke's products to such bottling process, and if so, which products; when this occurred; how Behnke's products were applied within the bottling process, and at which particular locations.

Bill Brown. This witness is an employee of Anheuser-Busch, and is supposed to testify about "the actual use of food-grade lubricants within the bottling industry," and "that when in use they may reasonably be expected to result, directly or indirectly, in its [sic] becoming a component or otherwise affecting the characteristics of food." *Respondent's Initial Prehearing Exchange*, at 5. It is not clear that Mr. Brown has knowledge of the Behnke products at issue in this case, nor is any information provided as to how Mr. Brown knows that such products "may reasonably be expected to result, directly or indirectly, in its [sic] becoming a component or otherwise affecting the characteristics of food." Complainant requests that the Court order Respondent to produce this information, as well as all supporting documentation.

Gary Hagerstrom. This witness is identified as a sales representative who "assisted in the sale of equipment to American Food Groups for use in its beef processing plant," and who "specified the lubrication needs for this equipment," and who "is familiar

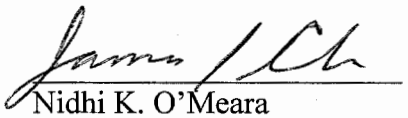
with the application of respondent's lubricants on the equipment used by American Foods Group." *Respondent's Initial Prehearing Exchange*, at 5-6. He is to testify about "the actual use of respondent's products ... at the American Food Groups' beef processing plant." *Id.*, at 6. Complainant requests that the Court order Respondent to produce all documents shared among Mr. Hagerstrom, Behnke and American Foods which discuss the "lubrication needs" for American Foods' equipment or the application of Behnke's products on such equipment, or which discuss the actual use of Behnke's products at American Foods' beef processing plant.

James Draheim, Craig Hoffman and Roger Nelson. Each of these witnesses is supposed to testify about the use or application of Behnke's products at particular facilities, or "the potential for [the products] to become part of the processed food." *Respondent's Initial Prehearing Exchange*, at 6. For each of these witnesses, Complainant respectfully requests that the Court order Respondent to describe in sufficient detail the particular use or application of Behnke's products at each facility, and explain how each of the Behnke products at issue has the potential to become part of the processed food. Complainant also requests that the Court order Respondent to produce true, accurate and complete copies of all documents shared between each of these witnesses, Behnke and the customers identified by Respondent in relation to these witnesses (Seneca Foods, Sara Lee, Badger Plastics & Supply Co.) in which the uses or applications of Behnke's products were discussed, or in which the potential for the products becoming part of the processed food was discussed.

VII. Conclusion

For all of the reasons set forth above, Complainant respectfully requests that the Presiding Administrative Law Judge GRANT Complainant's motion to strike Respondent's defenses, or in the alternative, that the Court GRANT Complainant's motion for discovery. Complainant also respectfully requests that the Court GRANT Complainant's Request for Additional Documents and Information.

Respectfully Submitted,



1/16/08

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

Date

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

CERTIFICATE OF SERVICE

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

Dated in Chicago, Illinois, this 16 day of January, 2008.

Patricia Jeffries-Harwell
Legal Technician