M&B McILNAY & BUTTON, LTD
ATTORNEYS AT LAW

1150 Washington Street
Grafton, WI 53024-1916
Phone: 262.376.1287
Fax: 262.376.1289
www.legalmms.com

June 26, 2008

VIA FEDERAL EXPRESS

Judge Barbara A. Gunning
Administrative Law Judge
US EPA
Mail Code 1900L
1200 Pennsylvania Ave., NW
Washington, DC 20460-2001

Re: *Behnke Lubricants Inc.*
Docket No. FIFRA-05-2007-0025

Dear Judge Gunning:

Enclosed find true and correct copies of Respondent's Post-Hearing Brief and Respondent's Proposed Findings of Fact and Conclusions of Law.

The originals and one copy of Respondent's Post-Hearing Brief and Respondent's Proposed Findings of Fact and Conclusions of Law were delivered to the Regional Hearing Clerk, Region 5, U.S. EPA via overnight mail on June 26, 2008. A true and accurate copy of same was delivered to Nidhi O'Meara via overnight mail on June 26, 2008.

Kindly acknowledge receipt of the enclosed by date stamping the extra copy of this letter and forwarding same to the undersigned in the envelope provided.

Should you have any questions, please do not hesitate to contact me.

Very truly yours,

Bruce A. McIlnay

BAM/dlp
Enclosures
cc: Regional Hearing Clerk, w/encls. (via federal express)
Nidhi O'Meara, w/encls. (via federal express)
Eric Peter, w/encls.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5

In the Matter of:

BEHNKE LUBRICANTS INC.
MENOMONEE FALLS, WISCONSIN

Docket No. FIFRA-05-2007-0025

Respondent.

RESPONDENT'S POST-HEARING BRIEF

Respondent Behnke Lubricants, Inc. ("Behnke"), by its undersigned attorneys, files this Post-Hearing Brief in the above-captioned matter pursuant to the May 1, 2008 Order Setting Briefing Schedule and Rule 22.26 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Consolidated Rules"), 40 C.F.R. 22.26.

I. STATEMENT OF THE CASE.

This proceeding arises under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §136 et seq. On May 7, 2007, Complainant United States Environmental Protection Agency ("EPA") filed a complaint against Behnke alleging eleven counts of distributing or selling unregistered pesticides in violation of FIFRA §§3(a) and 12(a)(1)(A), 7 USC §§136a(a) and 136j(a)(1)(A). Complainant proposes a total civil administrative penalty of $50,050.

Specifically, the complaint alleges Behnke's product literature and labeling and internet site constitute "advertisements" within the meaning of the FIFRA and the representations thereon regarding the benefits of Micronox® technology in Behnke's food grade lubricants JAX Poly-Guard FG-2, JAX Halo-Guard FG-2, JAX Halo-Guard FG-LT, JAX Magna-Plate 74 and JAX Magna-Plate 78 (hereafter collectively referred to as the "Lubricants") "claims, states or implies" that the Lubricants can or should be used "pesticides" within the meaning of FIFRA. Behnke denies its representations regarding its Lubricants "claims, states or implies" that the Lubricants can or should be used "pesticides" within the meaning of FIFRA. This is particularly true given its target market – sophisticated, savvy food and beverage processors -- is solely interested in controlling microbes in or on processed foods or beverages, which, by EPA's own definition, are not "pests" regulated by FIFRA. *See* 40 CFR §152.5(d).

A hearing on this matter was held in Waukesha, Wisconsin, on March 31-April 3, 2008. Based upon the entire record, Behnke respectfully requests that the Court enter an Order consistent with Respondent's Proposed Findings of Fact and Conclusions of Law filed herewith as further explained below.

II. LEGAL ANALYSIS.

The ultimate conclusion of law for determination by the Court in this case is whether Behnke distributed or sold unregistered "pesticides" within the meaning of FIFRA as alleged in the complaint. Application of the "on or in processed foods or beverages" exception to FIFRA raises an issue of first impression for this Court.

III. STATUTORY AND REGULATORY FRAMEWORK.

A. FIFRA.

FIFRA §3(a), 7 USC §136a(a), provides that no person may "distribute or sell" any

"pesticide" not registered under the Act with EPA. FIFRA §12(a)(1)(A), 7 USC §136j(a)(1)(A), more specifically states that "it shall be unlawful" to distribute or sell any "pesticide" that is not registered under §136a except to the extent authorized by the Administrator. The term "distribute or sell" means to "distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment ..." 7 USC §136(gg). *See also* 40 CFR 152.3. The Complaint alleges violations of FIFRA §§3(a) and 12(a)(1)(A).

The first critical question to be answered by the Court is whether Behnke's Lubricants are, in fact, "pesticides" within the meaning of FIFRA. The record evidence in this case shows that they are not. In that regard, Section 2(u) of FIFRA defines a "pesticide" in part as "any substance or mixture of substances *intended* for preventing, destroying, repelling, or mitigation any pest ..." 7 U.S.C. §136(u)(emphasis added). *See also* 40 CFR §152.3. In addition, Section 2(t) defines the terms "pest" to include "virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals)." 7 U.S.C. §136(t).

EPA regulation 40 CFR §152.5(d) specifically excepts from the definition of a "pest" any "fungus, bacterium, fungus or other microorganism if it is "on or in living man or other living animals" and those *"on or in processed food [and] ... beverages...."* (emphasis added).

Finally, 40 CFR §152.15(a)(1), provides in relevant part:

> ... A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:
> (a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):
> (1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide ...

The issue before the Court is whether in the circumstances shown in the record here, where the advertising of which EPA complains was directed solely to the food and beverage

processing market, do the claims made "claim, state or imply," that the Lubricants can or should be used as a pesticide. *In the Matter of Caltech Indus., Inc.*, Docket No. 5-IFFRA-97-006 ALJ EPA June 9, 1998, is instructive on this issue. In this case, EPA filed a complaint charging the respondent with selling and distributing an unregistered pesticide in violation of FIFRA. The Court held legitimate issues of fact precluded an accelerated decision. The respondent argued, and the Court concluded, that the "intended use" of the product must be considered applying the "reasonable consumer" objective standard set forth in *N. Jonas v. U.S. EPA*, 666 F.2d 829 (3rd Cir. 1981), and that the "reasonable consumer" *must be understood within the context of the market for the product*, such as the health care industry in the *Caltech* case.

Behnke respectfully submits that the evidence presented here shows that its advertising regarding the Lubricants at issue was directed solely to the food and beverage processing market, i.e., the ultimate consumers of these products. (Proposed Finding of Fact ("PFF") ¶ 36). Further, the evidence supports the finding that the concern of Behnke's customers within this market that would persuade them to purchase the Lubricants over other lubricants included their desire to prevent, destroy, repel, or mitigate, microbes "in or on" processed foods or beverages, and not with microbes, even human pathogens, in general. The record created at the hearing shows that reasonable customers within this limited market anticipate that the Lubricants, which are used only while their plants are processing foods or beverage, will migrate into the food during the course of usage. Therefore, the goal of these customers is to control microbes that may be transferred to the food when the Lubricants become a part of the food.

B. THE FEDERAL FOOD DRUG AND COSMETIC ACT ("FFDCA") 21 U.S.C. 321, ET SEQ.

The key to interpreting the ambiguity in FIFRA at the bottom of this case is whether the

Lubricants are "food additives" regulated under FFDCA. Under the FFDCA, Congress delegated to the Food and Drug Administration ("FDA") regulatory authority over, among other things, adulterated foods (FFDCA §402, 21 U.S.C. 342) and food additives (FFDCA §409, 21 U.S.C. §348).

Under the authority delegated to it under the FFDCA, the FDA has promulgated regulations governing both adulterated foods and food additives. The food additive regulations adopted under authority of §409 of the FFDCA are of direct relevance to the instant case. These regulations are found in CFR Title 21, Chapter I -- Food and Drug Administration, Department of Health and Human Services, Subchapter B – Food for Human Consumption, beginning with Part 170 -- Food Additives. Relevant sections provide:

§ 170.3 Definitions.

> For the purposes of this subchapter, the following definitions apply:
> * * *
> (c) Commissioner means the Commissioner of Food and Drugs.
> (d) As used in this part, the term act means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301-392).
> (e)(1) Food additives includes all substances not exempted by section 201(s) of the act, *the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. ....*
> * * *
> (3) A food contact substance is any substance that is intended for use as a component of materials *used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.*
> * * *
> (g) The word substance in the definition of the term "food additive" includes a food or food component consisting of one or more ingredients.
> * * *
> (i) Safe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general

recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

* * *

(m) Food includes human food, *substances migrating to food from food-contact articles*, pet food, and animal feed.

(Emphasis supplied).

§ 174.5 General provisions applicable to indirect food additives.

* * *

(c) The existence in this subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed as implying that such substance may be safely used as a direct additive in food.

(d) Substances that under conditions of good manufacturing practice *may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:*

(1) Substances generally recognized as *safe in or on food.*

* * *

(4) Substances permitted for use by regulations in this part and parts 175, 176, 177, 178 and § 179.45 of this chapter.

(5) Food contact substances used in accordance with an effective premarket notification for a food contact substance (FCN) submitted under section 409(h) of the act.

(Emphasis supplied).

§ 174.6 Threshold of regulation for substances used in food-contact articles.

Substances used in food-contact articles ... *that migrate, or that may be expected to migrate, into food* at negligible levels may be reviewed under § 170.39 of this chapter. ....

§ 178.3570 Lubricants with incidental food contact.

Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The lubricants are prepared from one or more of the following substances:

(1) Substances generally recognized as safe for use in food.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances identified in this paragraph (a)(3).

* * *

C. THE FOOD QUALITY PROTECTION ACT ("FQPA").

On August 3, 1996, Congress enacted the Food Quality Protection Act ("FQPA"), modifying FIFRA and the FFDCA. *See Registration Requirements for Antimicrobial Pesticide Products and Other Pesticide Regulatory Changes*, 64 Fed. Reg. 50672, 50673 (September 17, 1999). Prior to FQPA, the division of jurisdiction between EPA and the Food and Drug Administration ("FDA") over pesticide residues in food was controlled by complicated provisions of FFDCA. FQPA modified FFDCA to create clearer lines of jurisdiction. *Id.* at 50697.

When Congress enacted FQPA it expressly excluded the substances regulated under FFDCA from the definition of "antimicrobial pesticide," leaving the regulation of substances acting on microbes "on or in" processed foods and beverages to the FDA. Congress perceived no benefit in two distinct agencies of the federal government testing and passing on the safety and efficacy of the same products used within a specified industry, namely, the food and beverage processing industry.

Accordingly, FQPA amended FIFRA, 7 USC §136(mm)(1), such that the term "antimicrobial pesticide" means a pesticide that:

> (A) is intended to (i) disinfect, sanitize, reduce, or mitigate growth or development of microbial 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 regulations under section 409 of such Act [21*

U.S.C. §348].

(emphasis added).

D. FFDCA ANTIMICROBIAL REGULATION TECHNICAL CORRECTIONS ACT OF 1998 ("ARTCA").

In 1998, Congress passed the "Antimicrobial Regulation Technical Corrections Act of 1998" ("ARTCA") which supersedes the joint Policy Interpretation with regard to FFDCA regulatory authority over antimicrobial residues in food. 64 Fed. Reg. at 50698. ARTCA effectively transferred authority over a number of pesticide residues to the FDA which had originally been transferred to EPA by FQPA. *Id.* at 50673.

In its discussion of its proposed rules to implement the FQPA and ARTCA amendments to FIFRA, the EPA acknowledged "[t]he practical consequences of being included or excluded as an 'antimicrobial pesticide' are significant for both pesticide producers and the Agency. FIFRA section 2(mm) defines the term 'antimicrobial pesticide,' carefully delineating its boundaries to mesh with the practical implementation of section 3(h) requirements." 64 Fed. Reg. at 50677. When discussing the definition of "antimicrobial pesticide" adopted by Congress, the EPA stated:

> Having identified the universe of substances that, based upon the intended pesticidal purpose, are antimicrobial pesticides, the definition goes on in paragraphs (1)(B) and (2) to exclude certain pesticides from the definition of antimicrobial pesticide. *These exclusions may be characterized as use-based, that is, a pesticide is excluded because of how or where it is used*, and not because of the pests or purpose of use.

Id. (emphasis added).

The first such use exclusion identified by the EPA is the "food use" exclusion: "FIFRA section 2(mm)(1)(B) excludes from 'antimicrobial pesticide' those pesticides whose intended antimicrobial use is such that residues in food requiring regulation under sections 408 or 409 of

the FFDCA might result." *Id.*

The EPA recognized Congress was, among other things, attempting to avoid duplicative efforts by two federal agencies:

> 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. *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.*

Id. (emphasis added).

> *Given the food use exclusion, it is clear that the status of an antimicrobial product as an 'antimicrobial pesticide' within the meaning of FIFRA section 3(h) is not necessarily a permanent designation, but may shift according to its intended use. A product could be included or excluded from the definition if the intended use changes.*

Id. at 50678. (emphasis added).

EPA acknowledged it retained FIFRA authority for antimicrobial products "other than those used on processed food." *Id.* at 50698.

Despite EPA's apparent recognition that clear statutory language excludes products that "bear a food use" (*i.e.*, Behnke's Lubricants) from FIFRA regulation and registration, here it has decidedly ignored the plain meaning of the statute by disavowing the food use exclusion as to "antimicrobial pesticides."

IV. ARGUMENT

A. THE LUBRICANTS ARE NOT "PESTICIDES" WITHIN THE MEANING OF FIFRA.

1. *The Lubricants Are Not Intended to Control or Mitigate "Pests" Within the Meaning of 40 CFR §152.5, Because Microbes "On or In Processed Foods" Are Excepted From*

EPA's Definition of Pests.

The sale of only five Lubricants is at issue in this case-- JAX Poly-Guard FG-2, JAX Halo-Guard FG-2, JAX Halo-Guard FG-LT, JAX Magna-Plate 74 and JAX Magna-Plate 78 (Compl., T. 15). Therefore, any testimony unrelated to the sale of these specific products or unrelated to the specific dates the purported violations occurred is irrelevant and must be disregarded by the Court.

40 CFR §152.5(d) excludes from the definition of "pest," any "fungus, bacterium, fungus or other microorganism if it is "on or in living man or other living animals" and those *"on or in processed food [and] ..., beverages..."*

The record evidence shows Behnke's Lubricants are not "intended" for preventing, destroying, repelling, or mitigating any *"pest"* within the meaning of FIFRA §2u, 7 USC §136(u). The Lubricants cannot be pesticides because, to the extent the Lubricants have antimicrobial properties, the microbes intended to be controlled are solely those food borne microbes found "in or on processed foods."

The indisputable testimony of Troy Paquette, Behnke's Technical Director, show that the concern of Kraft Foods, which was the impetus for the development of Behnke's Micronox technology, was microbes in its soft cheeses. Likewise, Larry Cooper, a long-time employee of Quaker Oats and now a consultant in the food processing industry, described in detail how lubricants become part of the processed food products. Finally, Carter Anderson, Behnke's Vice President, who has years of experience working with Behnke's customers, testified to the likelihood that the Lubricants would become part of the food products, with specific examples of such cases in which he was directly involved. (PFF ¶¶ 121-22, 126-27).

In light of this proof," it logically follows that the Lubricants also fall within the

regulatory definition of "food" found in 21 CFR §170.3(m), *i.e.* "[f]ood includes human food [and] *substances migrating to food from food-contact articles* ... ." The only conclusion to be drawn from the record is that the Lubricants are indeed edible food articles and *are not*, therefore, subject to the same FIFRA registration as floor cleaners or wall sanitizers. Behnke's witnesses, as well as the testimony of Josh Rybicki of American Foods (Tr. 99-100), who was called by the EPA, provides substantial evidence that the Lubricants become a part of the processed foods and the microbes in question are, therefore, "on or in processed foods."

2. *Because the Lubricants Are Not Intended to Control "Pests," It Follows That the Lubricants Are Not Pesticides Within the Meaning of 40 CFR §152.3.*

The definition of pesticide is found in 40 CFR 152.3, and states, in relevant part, "Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any *pest*...." (Emphasis supplied). Since the microorganisms found "on or in processed food" are not pests within the meaning of FIFRA, it necessarily follows that the Lubricants are not pesticides within the meaning of 40 CFR 152.3.

3. *That the Lubricants Are Not Pesticides Is Further Supported By FIFRA's "Food Use" Exception From The Definition of Antimicrobial Pesticides Subject to FIFRA Regulation.*

In relevant part, 7 USC §136 provides that an *antimicrobial pesticide* means a substance that:

> (A) is intended to (i) disinfect, sanitize, reduce, or mitigate growth or development of microbial 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 346a of title 21 or food additive regulations under section 348 of title 21.*

Through the testimony of Messrs. Paquette, Peter, Anderson and Cooper, Behnke has demonstrated that its Lubricants are "food additives" subject to regulation under 21 USC §348, et seq. and, in fact, have been designated as such by the FDA.

The Lubricants must be FDA-approved for potential ingestion from incidental contact with processed foods or beverages. This means that the Lubricants are subject to tolerances in food additive regulations within the meaning of 21 USC §348, *et seq*.

The public safety purpose of regulating pesticide sales and distribution is served by subjecting "food use" products to the tolerances described in the exclusion of 7 USC §136(mm)(1)(B). Further, there is no efficacy need for pesticide regulation of these products. By definition, the Lubricants are sold only into the food and beverage processing industries. Unlike the typical consumer purchasing a disinfectant for home use, these are sophisticated buyers who are in a highly regulated industry subject to extraordinary liability if their products are contaminated. Indeed, Behnke contends EPA registration of its products as pesticides would have a chilling effect on their use in the food processing industry as it would imply the users were using a poison in food contact applications even though they met the tolerances established under §409 of the FFDCA.

The EPA recognized the logic of Congress' regulatory scheme in the EPA's discussion of its proposed rules to implement FQPA and the ARTCA:

> On October 30, 1998, Congress enacted the Antimicrobial Regulation Technical Corrections Act (ARTCA), which modified the Federal Food, Drug, and Cosmetic Act (FFDCA) to effectively transfer authority over a number of pesticide residues to FDA. Regulatory authority over these residues had originally been transferred to EPA by FQPA.

64 Fed. Reg. 50672, at 50673-74 (September 17, 1999).

> 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. *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.*

Id. at 50677(emphasis added).

Since the Lubricants are food additives within the meaning of §409 of the FFDCA, then it logically follows that the Lubricants are neither *antimicrobial pesticides* specifically, nor pesticides more generally, because the antimicrobial properties of the Lubricants are intended to control or mitigate microorganisms "on or in processed foods" only. EPA should not be allowed to make an end run around the Congressional intent evident in the plain language of the food use exclusion contained in 7 USC §136(mm)(1)(B).

B. STATEMENTS CONTAINED IN BEHNKE'S LABELING DID NOT LEAD A REASONABLE CONSUMER OF THE LUBRICANTS TO CONCLUDE THAT THE LUBRICANTS CAN OR SHOULD BE USED AS A PESTICIDE.

The gravamen of the EPA's case is that the information regarding the antimicrobial technology, Micronox®, incorporated into the Lubricants "claims, states, or implies (by labeling or otherwise) that the substance [the Lubricants] can or should be used as pesticides" *See* 40 CFR 152.15(a)(1). To that end, EPA presented *ad nausea* exhibits and testimony regarding Behnke's past promotion of the Lubricants and the concerns the same would raise if misunderstood by the consuming public at large.[1] The trouble with the EPA's approach is that it

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[1] With the benefit of 20:20 hindsight, perhaps Behnke could have avoided this entire litigation by prefacing all statements regarding its Micronox® technology with language such as:

> The intended use of [insert name of product] *may result or may reasonably be expected to result, directly or indirectly, in* [insert name of product] *becoming a component of*

completely ignores the sophistication and technical nature of Behnke's target market, described in detail by Messrs. Peter, Paquette, Anderson, Cooper and even, EPA's own expert, Dr. Tajah Blackburn, who testified as to her testing for microbes for Nestle. (Tr. pp. 522-23). The testing done by these sophisticated customers was expressly for microbes in or on processed foods and not in the Lubricants.

By definition, microorganisms "on or in processed food" do not constitute pests. It follows that specific information regarding the antimicrobial affects of the substance on microbes in processed foods where the substance may reasonably be expected to become a part of that food, does not "claim, state or imply that the product can or should be used as a pesticide."

Behnke respectfully submits that it would not be responding to the present EPA complaint had it used more precise language as suggested above to inform customers of the benefits of its Micronox®. Behnke further submits, however, that such precise language is unnecessary within the context of this case because of the limited market for the Lubricants, the sophistication of the buyers of the Lubricants, and the knowledge within the food processing industry that "the intended use of [insert name of product] *may result or may reasonably be expected to result, directly or indirectly, in* [insert name of product] *becoming a component of food.*"

Behnke only markets and sells its Lubricants for usage by the food and beverage processing industry. By virtue of the sale of its Lubricants to food and beverage processors only, any antimicrobial properties they may exhibit only relate to microbes "on or in processed" food

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food. When this happens, JAX Micronox® technology will mitigate or control the microbial population commonly found *on or in* the food undergoing processing in your plant.

or beverages, which are expressly excluded from the definition of "pest" under FIFRA as interpreted by EPA in 40 CFR 152.5(d).

EPA's "Label Review Manual" deals with the exception in 40 CFR §152.5(d): "Antimicrobial products used solely in processed foods or feeds, in beverages, or in pharmaceuticals" are "*not* pesticides under FIFRA and are regulated by FDA, not EPA." (CX50)(emphasis added).

The appropriate issue here is what a reasonable consumer of the Lubricants in its limited market understands about the intended use of the Lubricants from the information provided by Behnke. In the *Caltech* case, EPA filed a complaint charging the respondent with selling and distributing an unregistered pesticide in violation of FIFRA. The Court held legitimate issues of fact precluding accelerated decision were raised regarding the "intended use of" the alleged pesticidal product ("Hospital Cleaning Towels with Bleach") and the proper legal standard from which to determine such intended use. The respondent argued, and the Court concluded, that the "intended use" of the product must be considered applying the "reasonable consumer" objective standard set forth in *N. Jonas v. U.S. EPA*, 666 F.2d 829 (3rd Cir. 1981), and that the "reasonable consumer" must be understood within the context of the market for the product, such as the health care industry in the *Caltech* case.

Citing *Jonas*, the *Caltech* court stated : "[w]hether a product is a pesticide, is to be determined by all claims made for the product on labels or otherwise, *and the intent of the user, if the seller distributor has actual or constructive knowledge of the intent of the user.*" (emphasis added)(citations omitted). See *in the matter of Predex Corp.*, 1997 FIFRA LEXIS 6 (June 18, 1997).

A reasonable consumer in this industry is concerned with microbes contaminating the

processed food, of which the Lubricants may become a part.

Additionally, the evidence at hearing showed that Behnke's Lubricants are, first and foremost, developed, intended and sold as commercial lubricants for usage in food and beverage processing plants. The antimicrobial properties the Lubricants possess are an incidental benefit that protects against the Lubricant's cross-contamination of the food or beverages being processed. (PFF ¶ 26).

In the Complaint, EPA makes various allegations regarding Behnke's internet site (www.jax.com) and other non-Behnke sites. (*See* Compl. ¶¶66, 67, 176 and 178) . EPA alleges these sites constitute "advertisement as referenced in 40 CFR §168.22(a)" and "claim, state or imply" Behnke's Lubricants are pesticides. (¶¶70-73, 179, 180).

It is important for the Court to note EPA has alleged eleven counts on which Behnke sold or distributed unregistered "pesticides" on certain specified dates. None of the Internet site allegations in the Complaint involve the same dates the alleged eleven violations occurred. For this reason alone, these are irrelevant to this Court's inquiry into the eleven counts alleged against Behnke. Second, EPA has submitted no proof in support of the Motion that said Internet sites in any way related to the eleven sales or distributions at issue. Finally, there is no proof before the Court that any of Behnke's alleged customers were aware of these sites or its contents or, for that matter, aside from Behnke's own website, whether Behnke was aware of or responsible for the content on the dozen plus other websites alleged in the Complaint. Thus, this evidence is irrelevant to the claims at issue here and must be disregarded.

C. DETERMINATION OF PENALTY

The complaint proposed a total civil penalty in the amount of $50,050 or $4550 per Count. Behnke waived any challenge, argument or objection to this proposed penalty based on

or otherwise relating to the factors "the size of business of the person charged" and "the effect on the person's ability to continue in business" as set forth in Section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4). In the event Behnke is found liability for any of the violations alleged in the complaint, however, Behnke submits that the appropriate penalty is $0 or, at most, $2275 per violation, not $4550.

In accordance with the FIFRA Enforcement Response Policy (ERP), Table 3, the enforcement remedy for a total Gravity Value of 3 or below, is "No Action, Notice of Warning, or 50% reduction of the matrix value." At a minimum, a 50% reduction of matrix value is recommended where multiple count violations exist.

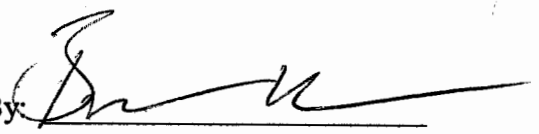
In determining the proposed penalty, Complainant assessed a culpability level of "2" against Behnke for each Count. Under the ERP, Level 2 is "Culpability unknown" or "Violation resulting from negligence." A Level 0 culpability, on the other hand, applies when the "Violation was neither knowing nor willful and did not result from negligence. Violator instituted steps to correct the violation immediately after discovery of the violation."

V. CONCLUSION.

For the reasons stated herein, Behnke respectfully requests that Complainant's complaint be dismissed on its merits, with prejudice.

Dated: June 24, 2008.

McIlnay & Button, Ltd.
Counsel for Behnke

By: 

Bruce A. McIlnay
Linda S. Isnard
Joseph F. Kirgues

McIlnay & Button, Ltd.
1150 Washington Street
Grafton, WI 53024
(262) 376-1287
(262) 376-1289 (fax)

CERTIFICATE OF SERVICE

The undersigned hereby certifies that he has caused a true and correct copy of foregoing RESPONDENT'S POST-HEARING BRIEF to be served upon the following on the date indicated below by either overnight mail or in person:

Regional Hearing Clerk (E-13J) (Original and one copy) (delivered in person)
U.S. Environmental Protection Agency, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

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

Nidhi O'Meara (C-14J), Associate Regional Counsel (delivered in person)
U.S. Environmental Protection Agency, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

Dated: June 26, 2008

Bruce A. McIlnay

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:

BEHNKE LUBRICANTS INC.
MENOMONEE FALLS, WISCONSIN

Docket No. FIFRA-05-2007-0025

Respondent.

RESPONDENT'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

Pursuant to the May 1, 2008, Order Setting Briefing Schedule in the above referenced matter and Rule 22.26 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules), 40 C.F.R. § 22.1-.32, Respondent Behnke Lubricants Inc. ("Behnke"), hereby files the instant Proposed Findings of Fact and Conclusions of Law:

I. PROPOSED FINDINGS OF FACT

1. Behnke owns and operates a place of business located at W134 N5373 Campbell Drive, Menomonee Falls, Wisconsin, 53051. Eric J. Peter (" Peter") is the president of Behnke. Behnke has been in business since 1955. (Transcript ("Tr.") 551)(RX 61, pg. 1).

2. Behnke manufactures JAX® branded lubricants for industrial uses and employs approximately 50 people with primary locations in Wisconsin and California, and sales representatives throughout the United States. (Tr. 554-56)(RX 61, pg. 2).

3. Behnke's lubricants were originally developed for use on heavy equipment, industrial machinery, heavy duty trucking, and farm and off highway construction machinery. Behnke manufactures and distributes lubricants as varied as engine oils, hydraulic fluids, gear box oils, conveyor lubricants, greases, way lubricants, transmission fluids and compressor oils. (Tr. 552, 555)(RX 61, pg 3.)

4. In approximately 1961, Behnke was providing lubricants for processing machinery for Swift, Armour, Hormel and numerous other meat processors for their shop and processing equipment. These food processing plants were inspected by the United States Department of Agriculture ("USDA"). At that time, it was determined by USDA that the lubricants used on the food processing equipment within these plants posed an actual and potential threat of contacting and becoming a part of the processed food product. With general industrial lubricants this could present a health hazard to consumers of the finished food product. (Tr. 560-62, 564-65)(RX 61, pg. 4).

5. In addition to the USDA, whose inspection authority included meat and poultry processors, the United States Food and Drug Administration ("FDA") regulated other food and beverage processing plants. In the early 1960s, FDA and USDA jointly promulgated regulations specifying chemical formulation tolerances for the lubricants that could be used in the food and beverage processing plants. (Tr. 560)(RX 61, pg. 5).

6. Under the FDA/USDA regulations, if the lubricants were industrial in nature and did not contain any poisonous or lethal substances, such as lead, antimony and other components, they could be used in the food processing plants. If, however, the chance of incidental contact with the food product itself was determined to exist, the lubricant was required to meet the new ingredient guidelines established by FDA with the

finished product chemistry to be confirmed and approved for listing by USDA. These "food grade" lubricants could only contain up to the maximum levels of ingredients specified by FDA for use in lubricants in incidental food contact under what is now 21 C.F.R. § 178.3570. These ingredients at the specified levels or tolerances were designated in the regulations. Also allowed (in the food grade lubricants) were 21 C.F.R. §182 items "generally regarded as safe," spawning the acronym "GRAS" to identify them. USDA developed a classification for food grade lubricants that was later designated as "H1." (Tr. 561-62, 749-50)(RX 61, pg. 6).

7. As FDA continued to test ingredients and add to the list of ingredients specified for use in lubricants in incidental food contact, Behnke remained intimately involved in development and formulation of improved lubrication products. It was common practice to submit as many as 15-20 lubricants per year to USDA laboratories for H1 certification. As the lubrication performance of the H1 products improved, acceptance of their use in plants. Thus the improvement in USDA H1 accepted lubricants' performance was integral in improving food safety, because it allowed greater use in all areas of processing facilities. (Tr. 562-65)(RX 61, pg. 9).

8. Behnke's customers demanded lubricants approved by USDA as H1 (food-grade) compliant. Behnke's experience producing these food grade lubricants dates back to the inception of the FDA/USDA regulation of lubricants with incidental food contact. (Tr. 560-62, 566)(RX 61, pg. 7).

9. All of Behnke's food grade lubricants at issue in this matter meet the tolerances required under 21 C.F.R. § 178.3570 and, therefore, have been deemed

acceptable by NSF as lubricants with incidental food contact (H1) for use in and around food processing areas. (Tr. 651-52)(RX 62, pg. 8).

10. A significant percentage of Behnke's business is the sale of H1 lubricants which are used to lubricate and protect mechanical equipment used in the food processing and bottling industries. A substantial portion of Behnke's budget is dedicated to the development and formulation of lubricants that are intended for use in food processing applications where incidental food contact and potential human ingestion of the lubricant is anticipated. (Tr. 559)(RX 62, pg. 4).

11. Behnke's market for its food grade lubricants includes bottlers, canners, meat packers, poultry processors, baked goods manufacturers, freezing plant operations and dozens more. The food processing related portion of Behnke's business accounts for over fifty percent of its gross revenues. (Tr. 559)(RX 61, pg. 27).

12. Virtually every one of the top 200 food processors in the world is using a JAX lubricant on some piece of processing machinery in their production facilities. (Tr. 557-59)(RX 61, pg. 26).

13. Troy Paquette ("Paquette") is employed as Behnke's Technical Director, a position he has held for the past nine years. (Tr. 739-40)(RX 62, pg. 1).

14. Paquette has a Bachelor of Science degree from the University of Wisconsin – Superior with a double major in Chemistry and Physics. He has worked in similar capacities in the lubricants industry since 1993 prior to joining Behnke. (Tr. 739-40)(RX 62, pg. 2).

15. As Behnke's Technical Director, Paquette is responsible for several areas within the company, including its research and development. (Tr. 741-43)(RX 62, pg. 3).

16. Behnke lubricants are formulated with either a mineral or synthetic base oil and other ingredients that, when combined, gives the finished products the unique properties required for a specific application. (Tr .574)(RX 61, pg. 28.)

17. Behnke's products are well known, distributed internationally and recognized for safety and compliance with all food grade lubricant regulations. Behnke takes its responsibility for food safety extremely seriously. (Tr .574)(RX 61, pg. 28).

18. In the late 1990's, USDA started taking a new approach to processing plant inspections and oversight. USDA required food processors to implement Hazardous Analysis and Critical Control Point ("HACCP") food safety standards. USDA's Food Safety and Inspection Service ("FSIS") reduced its plant inspections and discontinued the publication of its 'White Book' of approved products for use in processing plants, including H1 lubricants. (Tr. 568-69)(RX 61, pg. 11).

19. FDA requirements regarding formulation of food grade lubricants had not changed, but USDA no longer oversaw testing of finished formulations or publication of approved H1 lubricants. Instead, the processors were now responsible for ensuring that the materials used in their plants complied with the FDA regulations. As a result, lubricant suppliers such as Behnke had to certify compliance of their products and/or could have their finished products certified by an independent nongovernmental organization ("NGO") like NSF International ("NSF") or Underwriters Laboratories. By the mid 2000's, NSF had become the predominant NGO for H1 certification of lubricants. (Tr. 575-78)(RX 61, pg. 12).

20. For food grade applications, Behnke's lubricant formulations must be FDA compliant for incidental food contact. This requires that the additives and

chemistry of the finished product be within tolerances requested under 21 C.F.R. § 178.3570. Behnke must then certify this compliance directly to the customer or through a third-party laboratory, such as NSF. (Tr. 566-67)(RX 62, pg. 7).

21. Behnke must have a detailed understanding of the machinery and processes that JAX food grade lubricants must address for its customers including wear protection, corrosion resistance, oxidation prevention and other difficult issues in modern processing equipment. Behnke employs Lubrication Engineers who work hand-in-hand with customers' plant engineers and maintenance personnel to find or develop solutions for specific applications, which can vary tremendously from one environment to the next. It is not uncommon for Behnke personnel to work for hours or days at a time within its customers' plants to help insure a successful implementation of a machinery lubrication solution or plant program. (Tr. 774, 873- 80)(RX 61, pg. 13).

22. Due to the proximity of the lubricants to processed foods, the lubricants, although not intended, are expected to become a part of the processed food and to be ingested as part of the final food product. (Tr. 874, 878)(RX 61, pg. 14).

23. Paquette's responsibilities include working with Behnke's customers and its Lubrication Engineers to provide customers with lubricating solutions designed to provide consistent, efficient protection for their processing equipment in a wide variety of environments and applications. Even within the same industries, plants can vary greatly in their lubrication needs and how they apply Behnke products. (Tr. 749, 774, 872-74, 881)(RX 62, pg. 5).

24. Behnke's food processing customers are sophisticated consumers who are very demanding with regard to quality and performance. Paquette's job includes

formulation of lubricants that will exhibit the appropriate properties for the application and environment presented. Environmental concerns often include heat, humidity, and machine speed. (Tr. 878-80)(RX 62, pg. 6).

25. In or around 2001, Behnke was approached by Kraft Foods ("Kraft") which needed a lubricant for bearings used in their soft cheese production, where cheese and water splashed onto the bearings. Kraft discovered bacterial colonies, yeasts or molds in the bearing grease and was concerned with the health risk posed by contaminated grease becoming incorporated into its cheese. Kraft was concerned that microbes in the processed product would multiply within the grease, drip back into the processed cheese and thereby either increased the content of such microbes within the cheese to unacceptable levels or contaminated cheese that previously had not contained the microbes. The microbes at issue originated in the food product that was splashed onto the bearings. (Tr. 748-50)(RX 62, pg. 9).

26. Paquette researched how Behnke might reduce the risk of the grease becoming a host for food borne microbes, which, in turn, could migrate back into the food product due to incidental contact with the food. His goal was to mitigate this possible cross-contamination by developing lubricants that served Kraft's primary lubrication needs, while continuing to comply with FDA requirements for incidental food contact or ingestion. (Tr. 598-89, 748-50)(RX 62, pg. 10).

27. Behnke worked with several food processors, and through discussions and Behnke's knowledge of the various food processing methods and technologies, arrived at a combination of common lubricant additives that could be utilized in a variety of lubricants at levels below those allowed by FDA and would mitigate microbe

contamination in its customer's food and beverage products. (Tr. 749-52)(RX 62, pg. 11).

28. Based on discussions with Kraft and other food processors, it was determined that *Listeria monocytogenes*, *E. coli*, and *Salmonella* were the food borne bacterium of greatest concern in the meat and dairy processing industry. (Tr. 748-49)(RX 62, pg. 12).

29. Behnke provided Kraft with a modified sample of its JAX Poly-Guard FG-2 grease which already contained an FDA authorized food preservative (propyl p-hydroxybenzoate also referred to as "propyl paraben") for evaluation. The modifications to the formula were derived by introducing additional 21 C.F.R. § 178.3570 authorized additives at FDA allowable treat rates in addition to food additives which the FDA deemed "GRAS." (Tr. 752-53)(RX 62, pg. 13).

30. Kraft performed its own testing on this sample for its lubrication performance and microbial mitigation. (Tr. 756-57)(RX 62, pg. 14).

31. Behnke submitted samples utilizing the same formula to independent laboratories for evaluation specifically looking at *Listeria monocytogenes*, *E. coli,* and *Salmonella*. (Tr. 752-53)(RX 62, pg. 15).

32. Based on the laboratory results, Behnke incorporated the new additive formula into Behnke's food grade product line of products using the trade name "Micronox"® to identify the technology that mitigates microbes in their customers' foods and beverages. (Tr. 710)(RX 62, pg. 16).

33. Micronox,® is not a substance that exists separate from the lubricants that incorporate the technology. There is not a "formula" for Micronox® and one cannot purchase Micronox® as an additive for any other products. (Tr. 584-86)(RX 61, pg. 20).

34. Behnke's customers are not concerned with the lubricants as original sources of contamination, but rather as a medium for transfer of food borne microbes already found within the foods being processed. Therefore, the focus of the Micronox® technology has always been on mitigation or containment of microbes found in or on the customers' processed foods or beverages. (Tr. 586-89)(RX 62, pg. 17).

35. Behnke's food grade lubricants are sold exclusively in the food and beverage processing industries. Behnke's customers are sophisticated buyers who employ the services of scientists and physicians in their efforts to insure food safety. These customers are equipped to test for food borne microbes and identify potential "hot spots" for cross-contamination of their products. (Tr. 774-75, 778, 782)(RX 62, pg. 18).

36. Behnke undertook advertising and promotion of its food grade lubricants featuring the Micronox® technology in food and beverage processing plant machinery. Behnke felt the industry would benefit in terms of food safety by being aware that these lubricants were available, and Behnke felt it would be advantageous to promote the benefits of its Micronox® technology. As Micronox® was only of particular interest where there was a need to reduce the risk of cross contamination with food or beverage borne microbes, such advertising and promotional activities were aimed exclusively at the food and beverage processing markets. Behnke does not promote or sell lubricants incorporating the Micronox® technology to the general public or to industrial users outside the food and beverage processing markets. (Tr. 627-29, 866-67)(RX 61, pg. 21).

37. In approximately 2003, NSF informed Behnke that it had received complaints from Behnke's competitors regarding Behnke's promotion of its Micronox® technology. Apparently under pressure from these competitors, NSF took the position that Behnke's promotional materials constituted "pesticidal" claims in violation of FIFRA. Behnke disputed NSF's interpretation because, among other reasons, microbes "in or on processed foods" are by definition not "pests" under FIFRA. Nevertheless, NSF threatened to withdraw its H1 certification of Behnke's products unless Behnke altered its advertising and promotional materials regarding Micronox® technology. (Tr. 599-600, 612-13)(RX 61, pg. 22).

38. Behnke complied with NSF's first two demands until Behnke could get a clarifying interpretation of FIFRA and the Federal Food, Drug, and Cosmetic Act from a federal court. When, however, NSF took the position that Behnke could not refer to Micronox® on its labeling because the name allegedly implied a pesticidal purpose, Behnke commenced a declaratory judgment action in U.S. District Court for the Eastern District of Wisconsin seeking a judicial ruling on the limitations, if any, on Behnke's labeling under FIFRA. (Tr. 611-13)(RX 61, pg. 23).

39. By letter dated December 22, 2006, some five weeks after Behnke commenced its action against NSF, Behnke was first notified of the United States Environmental Protection Agency's ("EPA") intent to file this case. (Tr. 614-16, 618, 625)(RX 61, pg. 24).

40. In the spring and summer of 2007, many of Behnke's customers were inspected by a representative of the EPA Chicago regional office. One of these customers ceased buying from Behnke because they had been convinced by the EPA

representative that Behnke was selling an unregistered "pesticide." Behnke was advised that the customer had instead placed Petro-Canada on its approved vendor list. (RX 61, pg. 25).

41. Behnke does not, in its opinion, manufacture any products whose intended use is pesticidal in nature. Indeed, Behnke maintains it does not have any EPA registered pesticidal materials in its manufacturing facility. (RX 61, pg. 29).

42. On August 3, 2006, an inspector employed by the Wisconsin Department of Agriculture conducted an inspection under FIFRA at Behnke's establishment. (Stip. Fact 2).

43. During the August 3, 2006 inspection, the inspector collected physical samples of JAX Poly-Guard FG-2 and JAX Halo-Guard FG-2, which were packaged, labeled and ready for shipment or sale. (Stip. Fact 3).

44. During the August 3, 2006 inspection, the inspector also collected sample literature for the following Behnke products: JAX Poly-Guard FG-2, JAX Poly-Guard FG-LT, JAX Halo-Guard FG-2, JAX Halo-Guard FG-LT, and JAX Magna-Plate 74. (Stip. Fact. 4).

45. During the August 3, 2006, the inspector also collected invoices showing the shipment of JAX Poly-Guard FG-2, JAX Poly-Guard FG-LT, JAX Halo-Guard FG-2, JAX Halo-Guard FG-LT, and JAX Magna-Plate 74, which were offered for sale by Respondent. (Stip. Fact. 5).

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

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

proven especially effective in protecting JAX Poly-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

B. "Powerful Antimicrobial Performance"

C. "Added Step in Microbial Protection Programs"

D. The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.

(Stip. Fact 6).

47. The label on the JAX Poly-Guard FG-2 container, observed and collected by the inspector on August 3, 2006, states: "Advanced, Anti-Wear NSF H1, Food Machinery Grease with PTFE and Micronox Antimicrobial," "The bonus is an H1 lubricating grease with Micronox, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," powerful antimicrobial performance" and "added step in microbial protection programs." (Stip. Fact 7).

48. JAX Poly-Guard FG-2 is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136a(a). (Stip. Fact 8).

49. On or about March 3, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 to Perlick Corporation ("Perlick") located in Milwaukee, Wisconsin. (Stip. Fact 9).

50. On or about June 15, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 to Badger Plastics & Supply, Inc. ("Badger") located in Plover, Wisconsin. (Stip. Fact 10).

51. On or about August 3, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 by having JAX Poly-Guard FG-2 packaged, labeled and ready for shipment

or sale as its location of W134 N5373 Campbell Drive, Menomonee Falls, Wisconsin. (Stip. Fact 11).

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

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

B. The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.

(Stip. Fact 12).

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

54. JAX Halo-Guard FG-2 is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136a(a). (Stip. Fact 14).

55. On or about August 3, 2006, Respondent distributed or sold JAX Halo-Guard FG-2 by having JAX Halo-Guard FG-2 packaged, labeled and ready for shipment or sale at its location of W 134 N 5373 Campbell Drive, Menomonee Falls, Wisconsin. (Stip. Fact 15).

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

A. "JAX Halo-Guard FG greases incorporate JAX new, proprietary antimicrobial additive technology, Micronox, to provide antimicrobial protection for the product. A first in good-grade lubricants, JAX Micronox has proven especially effective in

protecting JAX Halo-Guard Greases against Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) over extended lubrication intervals."

B. The Literature also included Respondent's contact information such as phone number, facsimile number and Internet address.

(Stip. Fact. 16).

57. JAX Halo-Guard FG-LT is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136(a). (Stip. Fact. 17).

58. On or about June 27, 2006, Respondent distributed or sold JAX Halo-Guard FG-LT to Jennie-O Turkey Store ("Jennie-O") located in Willmar, Minnesota. (Stip. Fact. 18).

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

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

B. "JAX Magna-Plate 74 provides three major benefits to food and beverage processing plants....Micronox anti-microbial technology to provide antimicrobial protection for the product..."

C. "Powerful Antimicrobial Performance"

D. "Added Step in Microbial Protection Programs"

E. The literature also includes container sizes and part numbers in addition to Respondent's contact information, which includes a phone number, facsimile number and Internet address.

(Stip. Fact 19).

60. JAX Magna-Plate 74 is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136a(a). (Stip. Fact 20).

61. On or about March 3, 2006, Respondent distributed or sold JAX Magna-Plate 74 to American Foods Group ("American") in Green Bay, Wisconsin. (Stip. Fact 21).

62. On March 8, 2007, U.S. EPA conducted an investigation at American, located at 544 Acme Street, Green Bay, Wisconsin. (Stip. Fact 21).

63. During the March 8, 2007 investigation, American gave the inspector copies of two purchase orders showing that American had order JAX Halo-Guard FG-2 and JAX Magna-Plate 78 from the Respondent, dated December 19, 2006 and March 3, 2006. (Stip. Fact 23).

64. On March 16, 2007, the inspector received two pieces of literature (via mail) from American which were given to American by the Respondent. (Stip. Fact 24).

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

A. The packet included literature for Magna-Plate 78 Fluids, which states, among other things: "Antimicrobial Performance: Both products incorporate JAX new, proprietary antimicrobial additive technology, Micronox, for enhanced product protection against a wide variety of microbial agents, including yeasts, molds, gram-positive and gram-negative bacteria. A first in food grade lubricants, JAX Micronox provides significant knockdown performance and has proven especially effective against lysteria (Lysteria monocytogenes), E. coli (Escherichia coli) and salmonella (Salmonella typhimurium) on contact and over extended lubrication intervals."

B. This literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.

C. The packet also included literature for Magna-Plate 74, which states, among other things: "Antimicrobial Performance: JAX

Magna-Plate 74 incorporates JAX new, proprietary antimicrobial additive technology, Micronox, for enhanced antimicrobial protection against a wide variety of microbial agents, including yeasts, molds, and gram-positive and gram-negative bacteria. A first in food-grade lubricants, JAX Micronox provides significant knockdown performance and has proven especially effective against lysteria (Lysteria monocytogenes), E. coli (Escherichia coli) and salmonella (Salmonella typhimurium) on contact and over extended lubrication intervals."

D. This literature also included Respondent's contact information such as phone number, facsimile number and Internet address.

E. The packet also included literature for Halo-Guard FG which states, "JAX Halo-Guard FG provides Micronox microbial knockdown performance."

(Stip. Fact. 25).

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

A. A cover letter addressed to the customer which states: "First and foremost is Micronox, JAX advanced antimicrobial technology that provides immediate and significant knockdown performance on a wide spectrum of microbial contaminants. This development alone is providing HAACP programs a powerful new weapon in their ongoing battle against microorganisms."

B. The packet also included a sheet entitled "JAX Micronox Technologies," which describes in detail the enhanced antimicrobial capabilities of the Micronox additive system including a graph comparing Poly-Guard FG with competitors in efficacy against Listeria, E. Coli, and Salmonella.

C. The literature also included the Respondent's contact information such as phone number, facsimile number and Internet address.

(Stip. Fact 26).

67. On March 29, 2007, the inspector received another piece of literature from American, which was given to American by the Respondent. (Stip. Fact 27).

68. This literature was entitled "Technology Focus, JAX Micronox Technology, Introducing Micronox Technology in JAX Food-Grade Lubricants for

Microbial Knockdown Performance against Listeria, E.coli, Salmonella and other microorganisms" and includes, among other things:

A. A letter from Behnke Technical Director entitled: "What is JAX Micronox Technology: Re: Antimicrobial Usage in JAX Food-Grade Products."

B. Literature for Poly-Guard Greases.

C. Literature for Magna Plate 78.

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

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

F. Literature entitled "Independent Lab Results" which also makes references to JAX Poly-Guard FG-2.

G. Literature entitled "Food Industry Firsts" that states, among other things: "The first effective food-grade antimicrobial additive for lubricants with knockdown capabilities, effectively partnering lubricants into plant sanitation programs."

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

(Stip. Fact 28).

69. JAX Magna-Plate 78 is not registered as a pesticide under Section 3(a) of FIFRA, 7 U.S.C. § 136a(a). (Stip. Fact. 29).

70. Joshua Rybicki is employed in Inventory Control at the American plant located in Green Bay, Wisconsin. (Tr. 80-81).

71. Joshua Rybicki was at no time relevant empowered to make any decisions relating to what products were or were not allowed into the food manufacturing chain at American; that decision resided Dr. Moshini, American's Director of Food Safety. (Tr. 99).

72. American is limited in the number of lubricants it employs in its plant. In particular, American can only use lubricants that are H1 certified for incidental food contact. (Tr. 100).

73. The sanitizing and lubricating processes at American occur at two distinct and separate times. (Tr. 102-103).

74. American purchased products from Behnke's line of lubricants for their lubricating properties, not for a cleanup or sanitizing purpose. (Tr. 109).

75. On or about December 19, 2006, Respondent distributed or sold JAX Halo-Guard FG-2 to American in Green Bay, Wisconsin. (Stip. Fact. 30).

76. On or about December 19, 2006, Respondent distributed or sold JAX Magna-Plate 78 to American in Green Bay, Wisconsin. (Stip. Fact 31).

77. On or about March 5, 2007, Respondent distributed or sold JAX Magna-Plate 78 to American in Green Bay, Wisconsin. (Stip. Fact 32).

78. On or about March 3, 2006, Respondent distributed or sold JAX Magna-Plate 78 to American in Green Bay, Wisconsin. (Stip. Fact 33).

79. On March 8, 2006, US. EPA conducted an investigation at Badger, located at 3451 Johnson Avenue, Plover, Wisconsin. (Stip. Fact 34).

80. During the investigation on March 8, 2007, the inspector was taken to a supply area by Badger employees. (Stip. Fact 35).

81. The inspector observed four boxes, each containing ten 14-ounce cartridge tubes of JAX Poly-Guard FG-2 in the storage area. (Stip. Fact 36).

82. The inspector viewed a single tube from each of the four boxes in the storage room. (Stip. Fact 37).

83. All four cartridge tubes bore the same language: "Advanced, Anti-wear NSF H1, Food Machinery Grease with PTFE and Micronox Antimicrobial." "The bonus is an H1 lubricating grease with Micronox, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs." (Stip. Fact 38).

84. The four tubes of JAX Poly-Guard FG-2 observed by the inspector at Badger were identical to the physical sample of JAX Poly-Guard FG-2 that was obtained on August 3, 2006 during the Behnke inspection. (Stip. Fact 39).

85. During the visit on March 8, 2007, Badger also provided the inspector with a brochure. (Stip. Fact 40).

86. The brochure was entitled, "Food Grade Lubricants with Micronox™." (Stip. Fact 41).

87. The brochure included a document entitled "What is JAX Micronox Technology? Re: Antimicrobial Usage in JAX Food-Grade Products." (Stip. Fact 42).

88. The brochure also included a table and a graph. (Stip. Fact 43).

89. The brochure also included contact information for Respondent including Respondent's phone number, facsimile number, Internet, distributor information and product ordering options. (Stip. Fact 44).

90. On or about September 18, 2006, Respondent distributed or sold JAX Poly-Guard FG-2 to Badger in Plover, Wisconsin. (Stip. Fact 45).

91. On March 7, 2007, the State of Minnesota Department of Agriculture conducted an inspection at Jennie-O, located at 1530 30th Street SW, Willmar, Minnesota. (Stip. Fact 46).

92. During the March 7, 2007 inspection, the inspector viewed and photographed a cartridge tube of JAX Halo-Guard FG-LT. (Stip. Fact 47).

93. The labeling on the tube stated "JAX Halo-Guard FG-LT provides Micronox microbial knockdown performance." (Stip. Fact 48).

94. During the investigation, Jennie-O confirmed that JAX Halo-Guard FG-LT was ordered on or about June 2006. (Stip. Fact 49).

95. On March 7, 2007, US E.P.A. conducted an investigation at Perlick, located at 8300 West Good Hope Road, Milwaukee, Wisconsin. (Stip. Fact 50).

96. During the investigation on March 7, 2007, the inspector viewed a 14-ounce cartridge of JAX Poly-Guard FG-2. (Stip. Fact 51).

97. The cartridge included the following language: "Advanced, Anti-wear NSF H1, Food Machinery Grease with PTFE and Micronox Antimicrobial," "The bonus is an H1 lubricating grease with Micronox, JAX exclusive antimicrobial chemistry possessing true knockdown capabilities," "powerful antimicrobial performance" and "added step in microbial protection programs." (Stip. Fact 52).

98. The cartridge of JAX Poly-Guard FG-2 observed by the inspector at Perlick was identical to the physical sample of JAX Poly-Guard FG-2 that was obtained on August 3, 2006 during the Behnke inspection. (Stip. Fact 53).

99. Larry Cooper (" Cooper") is a self-employed owner of Tri City Supply. Tri City Supply is an industrial sales and repair company that also distributes JAX products. Prior to forming Tri City Supply, Cooper worked as an industrial maintenance mechanic for Quaker Oats and was later promoted to lead mechanic for the Mama

Celeste Pizza Department. Cooper began his employment with Quaker Oats in approximately 1990. (Tr. 818, 820, 846).

100. Cooper was among the personnel at the Quaker Oats plant in Jackson, Tennessee, responsible for maintaining the processing and packaging equipment. This responsibility included lubricating the equipment for the Aunt Jemima brand waffles, pancake and French toast and was later expanded to include responsibilities for the Mama Celeste Pizza Department. (Tr. 820-21).

101. As a lead mechanic in the Mama Celeste Pizza Department of Quaker Oats, Cooper led two or three mechanics on a night shift that cleaned and prepped the food processing equipment for the next day's shift. As part of this responsibility, Cooper oversaw the re-lubing of the food processing equipment before every shift. (Tr. 824-25).

102. Cooper received training from Quaker Oats on the responsibilities of an industrial maintenance mechanic to ensure compliance with USDA guidelines on lubricants and to oversee the lubricating procedures within the plant. (Tr. 821).

103. In 2000, Cooper accepted a position as maintenance coordinator in the Aunt Jemima Department of Quaker Oats. As maintenance coordinator, Cooper managed the entire food processing process for the Aunt Jemima line of products and was responsible for ensuring his Department's compliance with USDA guidelines on lubricants. (Tr. 826).

104. As maintenance coordinator, Cooper oversaw the training of Quaker Oats employees in the Aunt Jemima Department, and later the Mama Celeste Pizza and Mrs. Paul's Fish Departments, in proper lubrication procedures. (Tr. 828-29).

105. Cooper's responsibilities included ensuring that Quaker Oats remained compliant with USDA regulations. (Tr. 826).

106. As maintenance coordinator, Cooper was responsible for determining how and when food lubricant came into contact with processed food in the plant. (Tr. 830).

107. Instances of contact between food lubricant and processed food were known within Quaker Oats as incidents of "incidental contact." (Tr. 830-31).

108. In Cooper's five years as a maintenance coordinator for various departments within Quaker Oats, incidents of incidental contact in the plant would occur at a minimum of a couple of times a month. (Tr. 832).

109. Many of these instances were caused by over-lubrication of the equipment causing lubricant to come into contact with the processed food. (Tr. 832).

110. Other incidents of incidental contact resulted from lubricant traveling through exhaust air onto processed foods. At least one of these incidents took ten days to discover, far too late to prevent the product in question from potentially reaching consumers. (Tr. 844-45, 857).

111. The sanitizing and lubricating processes were distinct and separate processes at the Quaker Oats facility. (Tr. 824-25).

112. Incidental contact between processed food or beverages and lubricants occurs recurrently and predictably in food or beverage processing plants. (Tr. 103, 831-32).

113. In Cooper's time as a maintenance coordinator for Quaker Oats, instances of incidental food contact were reported by line mechanics, packagers, and consumers.

These instances included reports of physical clumps of grease or oil on the processed food. (Tr. 824, 825, 844).

114. In one instance, after the breakdown of a bearing in a toast conveyor, Cooper discovered a greasy surface on the production line. After investigating the breakdown, Cooper discovered a greasy film on the surface of a production line. Cooper determined that this greasy film was lubricant that had been deposited on the production line from bearings. (Tr. 839, 841).

115. After this incident, Cooper obtained JAX Halo-Guard in an effort to terminate the bacteria problems that stemmed from incidental food contact incidents. Subsequently, Cooper's Quaker Oats facility began using JAX lubricants for its Aunt Jemima products. (Tr. 842-43).

116. Cooper's company, Tri City Supply, became a distributor of JAX products when a client came to Tri City Supply in need of terminating bacteria in its food processing plant. Tri City Supply distributed JAX to this client to assist the client in transitioning away from using WD-40 as its lubricant given the frequent contact between the lubricant and the chickens processed in the plant. (Tr. 847, 849).

117. Carter L. Anderson ("Anderson") joined Behnke in 1984 as a salesman in the emerging food processing industry. Anderson continues to work for Behnke Lubricants in his current position as a Vice President focusing on sales marketing, distribution, equipment relationships and multinational accounts. (Tr. 862, 865).

118. Anderson is responsible for overseeing Behnke's lubricant sales department. This sales department calls directly on end-users of Behnke's lubricant products: the food-processing market. (Tr. 866-67).

119. Anderson is also responsible for overseeing Behnke's other marketing channel, manufacturer representatives. These representatives market Behnke's products to customers in the food-processing industry. (Tr. 867).

120. Anderson's sales persons and manufacturer representatives typically deal with engineering, maintenance, superintendents, quality control managers and other professionals from the food-processing industry when marketing their products. (Tr. 876-77).

121. In Anderson's time with Behnke, the food-processing industry has acquired a heightened awareness of the risks of food contamination within food-processing plants. As a result, end-users in the food-processing industry now require food grade products that are H1 certified to ensure the continued safety and integrity of their food-products by eliminating the risk of contamination from contact between the lubricants and the food. (Tr. 870-71).

122. Behnke's end-users frequently approach Anderson with concerns that despite their best efforts, the lubricants on their hydraulic systems, mechanical seals, sliding products, etc., continually come into contact with the food product. These end-users desire lubricants that can reduce the threat of the lubricant contaminating the food-product. (Tr. 873-74).

123. Behnke's relationship with its end-users is commonly extensive, as demonstrated by Behnke's Lube Guard Total Lubrication Program, which provides Behnke's customers with a comprehensive line of Behnke products for use throughout the customer's plant. (Tr. 878, 880).

124. Behnke's relationship with a new customer, from initial contact until implementation of Behnke's Lube Guard Total Lubrication program typically takes from six months to one year. (Tr. 881).

125. Anderson receives contacts from his customers regarding contact between the lubricant and food on average once or twice a month. (Tr. 883).

126. CBI: Please See Attached.

127. CBI: Please See Attached.

II. PROPOSED CONCLUSIONS OF LAW

1. Behnke is a "person" "in any state" within the meaning of 7 U.S.C. § 136(s).

2. Behnke's Micronox® technology is intended to "prevent or mitigate" microbes in or on "processed foods or beverages" within the meaning of 40 CFR §152.5(d).

3. Microbes "in or on" processed foods are not "pests" within the meaning of FIFRA Section 2(t) (7 U.S.C. §136(t)).

4. Behnke's Micronox®, therefore, is not a pesticide within the meaning of Section 2(u) of FIFRA (7 U.S.C. §136(u)).

5. For this reason, Behnke products at issue in this case are not pesticides as a result of their containing Micronox. ®

6. JAX Poly-Guard FG-2 is not a "pesticide" within the meaning of FIFRA.

7. JAX Halo-Guard FG-2 is not a "pesticide" within the meaning of FIFRA.

8. JAX Halo-Guard FG-LT is not a "pesticide" within the meaning of FIFRA.

9. JAX Magna-Plate 74 is not a "pesticide" within the meaning of FIFRA.

10. JAX Magna-Plate 78 is not a "pesticide" within the meaning of FIFRA.

11. Due to the regulation of the customers for JAX Poly-Guard FG-2, JAX Halo-Guard, JAX Halo-Guard FG-LT, JAX Magna-Plate 74 and JAX Magna-Plate 78 (the "Relevant Market") by FDA and/or USDA, the Court concludes as a matter of law that their concern in purchasing products containing Behnke's Micronox® is with the prevention, control and/or mitigation of microbes "in or on" their processed foods and/or beverages.

12. The Court concludes as a matter of law that the Relevant Market would not read, interpret or understand any of the labeling presented at hearing to claim, state, or imply that JAX Poly-Guard FG-2, JAX Halo-Guard, JAX Halo-Guard FG-LT, JAX Magna-Plate 74 or JAX Magna-Plate 78 can or should be used as a pesticide within the meaning of 40 C.F.R. §152.15(a)(1).

13. Therefore, within the Relevant Market, including the customers identified in Claimant's Complaint herein, the Court concludes as a matter of law that the labeling presented at the hearing herein do not transform JAX Poly-Guard FG-2, JAX Halo-Guard, JAX Halo-Guard FG-LT, JAX Magna-Plate 74, JAX Magna-Plate 78 and/or Micronox® into pesticides requiring registration under FIFRA Section §136a (7 USC §136j(a)(1)(A)).

14. Based on the foregoing conclusions, the Court further concludes:

a. Count I: Respondent did not distribute, offer for sale or sell JAX Poly-Guard FG-2 on August 3, 2006 in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

b. Count II: Respondent did not distribute, offer for sale or sell JAX Halo-Guard FG-2 on August 3, 2006 in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

c. Count III: Respondent did not distribute, offer for sale or sell JAX Halo-Guard FG-2 on December 19, 2006 to American in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

d. Count IV: Respondent did not distribute, offer for sale or sell JAX Magna-Plate 78 on December 19, 2006 to American in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

e. Count V: Respondent did not distribute, offer for sale or sell JAX Magna-Plate 78 on March 5, 2007 to American in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

f. Count VI: Respondent did not distribute, offer for sale or sell JAX Magna-Plate 78 on March 3, 2006 to American in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

g. Count VII: Respondent did not distribute, offer for sale or sell JAX Magna-Plate 74 on March 3, 2006 to American in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

h. Count VIII: Respondent did not distribute, offer for sale or sell JAX Poly-Guard FG-2 on September 18, 2006 to Badger in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

i. Count IX: Respondent did not distribute, offer for sale or sell JAX Poly-Guard FG-2 on June 15, 2006 to Badger in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

j. Count X: Respondent did not distribute, offer for sale or sell JAX Halo-Guard FG-LT on June 27, 2006 to Jennie-O in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

k. Count XI: Respondent did not distribute, offer for sale or sell JAX Poly-Guard FG-2 on March 3, 2006 to Perlick in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA.

15. The Court further concludes that Respondent acted in good-faith in attempting to conform its labeling to the demands of both NSF and the EPA and any violation of labeling regulations was inadvertent, did not pose a risk to the consuming public, and did not result from a knowing or flagrant violation of such regulations. As a result, the Court, if presented with a violation, would find that the Gravity Value under the FIFRA Enforcement Response Policy would be "0." As a result, no penalty would be warranted in the event a violation had been found.

III. PROPOSED ORDER

Upon the foregoing Findings of Fact and Conclusions of Law,

IT IS HEREBY ORDERD, that Claimant's complaint herein is dismissed and judgment be granted in favor of Respondent for statutory costs.

Dated: June 26, 2008.

McIlnay & Button, Ltd.
Counsel for Behnke

By: _____
Bruce A. McIlnay
Linda S. Isnard
Joseph F. Kirgues

McIlnay & Button, Ltd.
1150 Washington Street
Grafton, WI 53024
(262) 376-1287
(262) 376-1289 (fax)