UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:

BEHNKE LUBRICANTS INC.
MENOMONEE FALLS, WISCONSIN

Docket No. FIFRA-05-2007-0025

Respondent.

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

Respondent Behnke Lubricants, Inc., through its undersigned attorneys, McIlnay & Button, Ltd., hereby files its response to Complainant's Motion to Strike Respondent's Affirmative Defenses and Motion to Compel Discovery.

INTRODUCTION

On May 7, 2007, Complainant United States Environmental Protection Agency ("EPA") filed a Complaint in this civil administrative penalty proceeding against Respondent Behnke Lubricants, Inc. ("Behnke) which alleges eleven violations of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") §§3(a) and 12(a)(1)(A), 7 USC §§136a(a) and 136j(a)(1)(A). EPA alleges, in sum, that Behnke sold or distributed "pesticides" not registered under Section 3 of FIFRA. More specifically, Complainant contends Behnke's internet site, product literature and labeling 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 Poly-Guard FG-LT, 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") constitute "claims, states or implies" that the Lubricants are "pesticides" within the meaning of FIFRA.

In its Answer, Behnke asserted seven affirmative defenses to the Complaint. EPA has now filed a motion to strike Affirmative Defenses 3, 4, 5 and 6 as "legally insufficient."[1] Affirmative Defenses 1, 2 and 7 are, therefore, not at issue with regard to the motion to strike. EPA also moves for discovery of information regarding Affirmative Defenses 1, 2, 5, 6 and 7.

For the following reasons, EPA's motions should be denied or, in the alternative, held in abeyance until the Court rules on Complainant's pending Motion for Accelerated Decision on Liability and on Affirmative Defenses.

RELEVANT STATUTES

FIFRA *§3(a)*, 7 USC §136a(a), provides that no person may "distribute or sell" any "pesticide" not registered under the Act. 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 Complaint alleges violations of FIFRA §§3(a) and 12(a)(1)(A). Thus, the pivotal issue in this case is

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[1] Behnke's Affirmative Defenses are as follows:

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.

whether, in fact, Behnke distributed or sold unregistered "pesticides" within the meaning of FIFRA.

DISPUTED ISSUE OF FACT NO. 1: Behnke contends there is a disputed issue of fact whether its products are, in fact, "pesticides" or are otherwise exempt from FIFRA regulation.

"*Pesticide*" means, in relevant part:

> (1) any substance or mixture of substances *intended* for preventing, destroying, repelling, or mitigation any *pest*, ...

FIFRA §2(u), 7 USC §136(u)(emphasis added). *See also* 40 CFR §152.3.

DISPUTED ISSUE OF FACT NO. 2: There is a disputed issue of fact whether the Behnke's Lubricants are "intended" for preventing, destroying, repelling, or mitigating any pest within the meaning of FIFRA §2u. Behnke will submit evidence at hearing that its 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.

"*Pest*" is further defined, in relevant part, as:

> (2) any other form of terrestrial or aquatic plant or animal life or 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 declares to be a pest under section 136w(c)(1)...

FIFRA §2(t), 7 USC §136(t). *See also* 40 CFR §152.5(c).

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* or processed animal feed, *beverages*, drugs, and cosmetics. " (emphasis added).

DISPUTED ISSUE OF FACT NO. 3: There is a disputed issue of fact whether Behnke's Lubricants "destroy, repel or mitigate" any "pest" within the meaning of FIFRA. Behnke will show it only markets and sells its Lubricants for usage by the food and beverage processing industry. Behnke contends (and will prove) by virtue of the sale of its Lubricants to food and beverage processors *only* that any antimicrobial properties they may exhibit only relate to microbes "on or in processed" food or beverages, which are expressly excluded from the definition of "pest" under FIFRA as interpreted by EPA in 40 CFR 152.5(d).

Behnke respectfully submits there is good reason for EPA to exclude microbes found on or in processed foods or beverages from the definition of "pests." When Congress enacted the Food Quality Protection Act of 1996 it expressly excluded the substances regulated under the Food, Drug, and Cosmetic Act from the definition of "antimicrobial pesticide," leaving the regulation of substances acting on microbes "on or in" processed foods and beverages to the Food and Drug Administration. Congress correctly 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. *See infra* pp. 5-6. No public good could be served from such duplicative regulatory authority and it could only burden tax payers and businesses with wasteful costs.

Accordingly, under FIFRA, 7 USC §136(mm)(1), 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).

DISPUTED ISSUE OF FACT NO. 4: Behnke contends (and will show) its Lubricants are not exempt from the food additive regulations under section 348 of title 21. Specifically, Behnke will show its Lubricants are "food additives" subject to regulation under 21 USC §348, *et seq*. and have been designated as such by the FDA.

At all times relevant to these proceedings, Behnke has vigorously disputed whether it has any obligation in the first instance to register its Lubricants as "pesticides" under FIFRA. As further articulated in its Answer, all the Lubricants are sold and used *only* in food and beverage processing plants. They are also 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 meaning of 21 USC §348, *et seq*.

Although EPA contends otherwise, there are issues of statutory ambiguity and consequential disputed issues of material fact and law at play in this case. In the EPA's discussion of its proposed rules to implement the Food Quality Protection Act of 1996 ("FQPA") and the Antimicrobial Regulation Technical Corrections Act ("ARTCA") amendments to FIFRA, EPA acknowledged that "[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. 50672, at 50677 (September 17, 1999).

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 section 408 or 409 of the FFDCA might result." *Id.*

The EPA recognized that in creating this use exclusion, 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).

As will be further explained in response to EPA's Motion for Accelerated Decision, despite its own Agency's recognition that clear statutory language excludes products that "bear a

food use" (including Behnke's Lubricants) from FIFRA regulation and registration, EPA here has decidedly ignored the plain meaning of the statute by disavowing the food use exclusion as to "antimicrobial pesticides" by prosecuting Behnke and now contending the definition of "antimicrobial pesticide" is irrelevant to this case. *See Declaration of Bruce A. McIlnay* submitted herewith.

BEHNKE'S AFFIRMATIVE DEFENSES

Aff. Def. Nos. 1, 2, 3, 4 and 7

Behnke's Affirmative Defenses Nos. 1, 2, 3, 4 and 7 are interrelated; Behnke's alleges affirmatively its products (Aff. Def. 1) are not "pesticides"; (Aff. Def. 2), do not contain a "pesticide"; (Aff. Def. 3), are not "antimicrobial pesticides"; and (Aff. Def.4) are not "pesticidal chemicals" subject to regulation under FIFRA because, by definition, (Aff. Def. 7) microorganisms "on or in processed" food and beverages are not "pests" within the meaning of FIFRA, especially as defined in 40 CFR §152.5(d). Why EPA takes issue with Affirmative Defenses Nos. 3 and 4, but not 1, 2, or 7 belies common sense. They are all interrelated as summarized in the "Relevant Statutes" section above.

Nos. 5 and 6

Behnke also affirmatively alleges (Aff. Def. 5) its products are "food additives" regulated by the FFDCA; and (Aff. Def. 6); their intended use is as a lubricant and they are formulated to protect against cross-contamination of processed foods and beverages. Proof that Behnke's products are "food additives" subject to regulation under 21 USC §348 is directly relevant to its exclusion from the definition of "antimicrobial pesticide" under FIFRA. The "intended use" defense articulated in Affirmative Defense No. 6 directly relates to whether, in the first instance, Behnke's products are "pesticides" within the meaning of FIFRA.

For these reasons, it is clear all of Behnke's affirmative defenses interrelate. Since microorganisms "on or in processed" food and beverages are not "pests" within the meaning of FIFRA , it necessarily follows that the ability of Behnke's Lubricants to resist microorganism on or in processed food does not make the Lubricants "pesticides." Further, because the Lubricants are subject to tolerances under 21 CFR §178.3570, they are not "antimicrobial pesticides" or "pesticidal chemicals" within the meaning of FIFRA. Therefore, this Court should not strike Behnke's Affirmative Defenses nos. 3-4. EPA's attempt to "divide and conquer" by treating these defenses as separate and distinct, defies common logic.

Because the Lubricants are intended solely for use within the food and beverage processing industries, any claims contained within its labeling or advertising are necessarily limited to organisms found in or on processed foods. Therefore, the unavoidable implication is that Behnke's claims regarding the Lubricants, which provide the basis of the EPA's complaint, are not "pesticide" claims. Behnke's claims, by definition, do not relate to pests within the meaning of FIFRA.

As alleged in Affirmative Defense no. 5, although Behnke's products are "food additives" regulated by the FFDCA does not in and of itself necessarily except the products from FIFRA regulation, evidence relating to Behnke's "food additive" certification directly relates to whether the Lubricants are "antimicrobial pesticides" within the meaning of 7 USC §136(mm). Behnke contends they are not, which is consistent with Congress' regulatory scheme in delegating regulatory authority solely to the FDA over certain food uses.

Finally, Affirmative Defense no. 6 is merely a factual claim that will be supported by testimony and documents at hearing.

BEHNKE'S FACTUAL POSITION REGARDING THE LUBRICANTS.

All following facts and contentions will be further supported and expanded upon by testimony and documentary evidence introduced at hearing in this matter. Further, affidavits will be submitted in support of these contentions, particularly Behnke's affirmative defenses, in opposition to Complainant's Motion for Accelerated Decision on Liability and on Affirmative Defenses:

Behnke is a leading supplier of food-grade lubricants to food and beverage manufacturers worldwide. Behnke does not sell the Lubricants to individual consumers, its sells only to commercial users, namely, food and beverage plants.

The primary use (and "intended purpose") of Behnke's Lubricants is to protect components of equipment in food and beverage manufacturing plants from wear, corrosion, oxidation and heat. The products are further formulated to have antimicrobial properties as to microorganisms generally found on or in processed foods and beverages. In their intended use, the Lubricants do come into contact with the processed foods and beverages. Thus, the Lubricants could be a "carrier for cross-contamination" with processed foods and beverages. Nevertheless, Lubricants primarily are sold as "lubricants," and not for their antimicrobial properties.

Because it is reasonably foreseeable the Lubricants may become a part of the processed food or beverages during their normal use, they are regulated by the FDA under §409 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Behnke's Lubricants must meet the requirements of 21 USC §348 or they will be deemed "unsafe." They are, therefore, formulated

entirely from ingredients which are subject to applicable FDA tolerances under 21 CFR §178.3570.[2]

Because Behnke's trade literature mentions the advantages of Micronox® technology in protecting against microbial contamination found on or in processed foods, EPA alleges Behnke is making "pesticidal" claims pursuant to 40 CFR 152.15. However, the lubricants are neither "antimicrobial pesticides" under 7 USC 136(mm) nor are they "pesticide chemicals" under 21 USC §321(q)(1)(a). Indeed, because such claims can only be construed within the context of the limited uses of the Lubricants, they are not even "pesticides" because the microbes to which they are subjected and for which the claims are made are those found "on or in processed" foods and beverages. As such, these microbes are not "pests" within the definition found in 40 CFR §152.5(d). Thus, any claims Behnke makes regarding such microbes are not pesticidal claims in their intended use.

In the Complaint itself, EPA refers to product labeling/literature that refer to "Micronox® technology providing antimicrobial protection *for the product.*" Complaint ¶18, 31, 41, 55, 65. "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." *Id.* Behnke's Answer essentially admits all allegations relating to its product labeling and promotion.

Behnke does not dispute that some of its literature/labeling refers to the "antimicrobial performance" of its Micronox® technology against yeasts, molds, gram-positive and gram-negative bacteria, particularly *Listeria*, *E. coli* and *Salmonella*; or its statement that the extra performance of its lubricants "effectively partner[ed] lubricants into plant sanitation programs."

[2] Compliance with the FDA tolerances are monitored by NSF, a nongovernmental organization that certifies the Lubricants as eligible for its H-1 Food Grade designation.

(Complaint, ¶86). Behnke does not dispute the promotion of the antimicrobial properties of its Micronox® technology. However, EPA's complaint is not that Behnke's products contain Micronox® technology with antimicrobial properties, but that Behnke "advertised" such capabilities without registering the technology as a "pesticide" under FIFRA.

The identical product could, however, be sold, according to the EPA, without registration if Behnke simply would not advertise the antimicrobial properties of its products. Therefore, there exists a material issue regarding the intent and interpretation of Behnke's labeling and advertising in the context with the Lubricants' intended use.

RESPONDENT'S MOTION TO STRIKE MUST BE DENIED

The Consolidated Rules of Practice do not specifically provide for the use of motions to strike in administrative proceedings. The only relevant provision is Rule 22.16 which addresses the general filing of motions. *In the Matter of County of Bergen*, Docket No. RCRA-02-2001-7110, 2002 EPA ALJ LEXIS 13, at *6-7 (ALJ, March 7, 2002)(Order denying Motion to Strike). Nonetheless, an administrative law judge may refer to the Federal Rules of Civil Procedure for guidance on such motions. *In re Lazarus, Inc.*, 7 E.A.D. 318, 330 n.25 (EAB 1997).

Fed. R. Civ. P. 12(f) provides, in relevant part:

> ...the court may order stricken from any pleading any *insufficient defense* or any redundant, immaterial, impertinent, or scandalous matter.

(emphasis added).

EPA relies on the "insufficient defense" portion of the rule in support of its motion to strike affirmative defenses nos. 3, 4, 5 and 6.

Motions to strike are "generally disfavored because they are a drastic sanction and because they are often employed as a delay tactic." *Bergen, Id.* (citing 5A Wright & Miller, Federal Practice and Procedure: Civil 2d §1380 (1990)). *See also In re Sender*, 423 F. Supp. 2d

1155, 1163 (D. Colo.)(2006). Such motions also run counter to the "general policy that pleadings should be treated liberally and that a party should have the opportunity to support his contentions at trial." *Id.* (citing *Oliner v. McBride's Industries, Inc.*, 106 F.R.D. 14, 17 (S.D.N.Y. 1985)). Therefore, a motion to strike a defense can only be granted "if that defense is *clearly insufficient* as a matter of law." *Id.* (citations omitted)(emphasis added). Such is not the case here which will be further expanded upon in opposition to Complainant's Motion for Accelerated Decision.

It is important to consider an affirmative defense is different from a denial. An affirmative defense is a basis for denying liability even if the facts of a complaint are true, while a denial simply denies the facts of a complaint. *In re Sender*, 423 F. Supp. 2d at 1163. The most common affirmative defenses are those mandated by statute, e.g., lack of jurisdiction, insufficiency of process, failure to state a claim, etc. *See, e.g.,* Fed. R. Civ. P. 12(b). The Consolidated Rules do not have a counterpart to Rule 12(b), but only require, in general, that an answer "contain the circumstances or arguments which are alleged to constitute the grounds of any defense." 40 CFR §22.15(b).

Hence the purpose for the inclusion of the seven "affirmative defenses" in Behnke's answer. While perhaps not technical "affirmative defenses" within the meaning of Fed. R. Civ. P. 12(b), they do summarize the circumstances and arguments constituting the grounds for challenging portions of EPA's prima facie case as required by Rule 22.15(5)(b). To "strike" them from the Answer would have no substantive value in this case; they will continue to serve as the foundation for Behnke's contention that its Lubricants are not "pesticides" within the meaning of FIFRA, which serves as the foundation of EPA's prima facie case, and Behnke should have the opportunity to support its contentions at hearing. *See In the Matter of Dearborn*

Refining Co., Docket No. RCRA-05-2001-0019, 2003 EPA ALJ LEXIS 10, at *7 (ALJ, January 3, 2003).

By way of example, in *Sender* the plaintiff contended affirmative defenses rebutted one or more elements of the prima facie cases of a specific claim and, therefore, should be stricken as redundant with the denials. The Court disagreed stating, "[a] defense should not be stricken if there is any real doubt about its validity, and [t]he benefit of any doubt should be given to the pleader." *Id.* (quotations omitted). Further, since it is "often unclear whether a defendant should properly plead a[n] argument as a denial or a defense, and because a defense not plead is waived, a cautious pleader will often err on the side of labeling an argument as a defense" and, therefore, there is no reason to penalize the pleader by granting a motion to strike. *Id.* (quotes omitted). The Court also cited support for the proposition that the federal rules allow a defendant to plead an affirmative defense that is also a denial and redundant allegations need not be stricken if they cannot prejudice the adverse party. *Id. at* 1163-64.

In County of Bergen, the judge refused to strike defenses even though the respondent was unlikely to be successful thereon, because "the possibility exists that once the record has been more fully established and respondent is able to further develop its arguments, respondent could successfully provide its case." *Id.*, 2002 EPA ALJ LEXIS 13, at *9-10 (citing *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990). As to the insufficiency or immateriality of a defense, such motions are not to be granted when there remains a genuine issue of disputed material fact. *In the matter of Century Aluminum of W. Va., Inc.*, Docket No. CAA-III-116, 1999 EPA ALJ LEXIS 26, at *2 (ALJ, June 25, 1999)(Order granting motion to strike). Further, courts are to refrain from evaluating the merits of a defense where the background of a case is not adequately developed. *In the Matter of Franklin and Leonhardt*

Excavating Co., Inc., Docket No. CAA-98-011, 1998 EPA ALJ LEXIS 126, at *10-11 (ALJ, December 7, 1998).

EPA's contention that it is "unnecessary for this Court to engage in the time-consuming task of fact-finding" on these defense defies comprehension. (Motion to Dismiss, p. 13). EPA has no basis for seeking to dismiss the very foundation of Behnke's defense in this matter particularly in the confines of a Motion to Dismiss.

As further explained above, Affirmative Defenses 3-6 all have relevance to the pivotal issue of whether Behnke's Lubricants are "pesticides" within the meaning of FIFRA. EPA's contentions otherwise ignore the very representations Behnke has made to this effect both before and after the commencement of this proceeding. EPA's self-serving contention that these defenses are "purely legal arguments" that should be stricken to avoid unnecessary expenditure of judicial resources runs counter to the requirement in 40 CFR §22.15(c) that answers include "*arguments* which are alleged to constitute the grounds of *any defense*." 40 CFR §22.15(b) (emphasis added); (Motion to Dismiss, p. 13 no. 4). Most affirmative defenses, in fact, are legal arguments applied to the facts of the case.

EPA seeks an Order striking certain of Behnke' affirmative defenses "because these defenses are insufficient as a matter of law, and there in no possibility that they can relieve Behnke of its liability for the violations alleged in the Complaint." That is not true for all the reasons articulated above.

EPA does not dispute Aff. Def. 1 (Behnke's products are not "pesticides") or Aff. Def. 2 (Behnke's products do not contain a "pesticide"). It does take issue, however, with Aff. Def. 3 ("Behnke's products are not "antimicrobial pesticides") and Aff. Def. 4 (Behnke's products are not "pesticide chemicals." The problem with this approach is that it attempts to judge the facts

of this case in a vacuum rather than within the context of the full regulatory scheme adopted by Congress regarding antimicrobial claims.

Behnke is in the awkward position of having to dispute the legal sufficiency of its defenses in opposition to a simultaneous Motion to Strike and Motion for Accelerated Decision. Same or similar arguments are raised by EPA in support of its motion for accelerated decision as to the affirmative defenses. Judicial efficiency would be served by the Court's consideration of Behnke's defenses on the Motion for Accelerated Decision, not the Motion to Dismiss.

An affirmative defense is insufficient, as a matter of law, only if the defense cannot succeed under any circumstance. *United States v. Smuggler-Durant Mining Corp*, 823 F. Supp. 873 (D. Colo. 1993). If a defense may be relevant, there are other contexts within which the sufficiency of the defense can be more fully tested with the benefit of a fuller record, e.g., on a motion for summary judgment. *United States v. Martell*, 844 F. Supp. 454, 457 (N.D. Ind. 1994). When the sufficiency of the defense depends upon disputed issues of fact or questions of law, a motion to strike an affirmative defense should not be granted. *Id.* Otherwise, the Court must accept as true, Behnke's allegations that the Lubricant's are not intended to affect "pests" and that its claims are not aimed at microorganisms other than those found "on or in" processed foods and beverages.

Unlike an affirmative defense relating to a statute of limitations, this Court cannot look at the pleadings alone to determine, as a matter of law that Behnke's defenses cannot succeed. Further, because of the need for the submission of supplemental affidavits supporting the existence of material issues of fact to counteract EPA's claim they are "insufficient as a matter of law," the affirmative defenses should more appropriately considered within the context of Complainant's Motion for Accelerated Decision.

Behnke contends there are numerous disputed issues of fact in this case. *See supra* pp. 2-5. For example, a disputed issue of fact exists whether its Lubricants are "intended" for preventing, destroying, repelling, or mitigating any pest thereby excluding the Lubricants from the definition of "pesticide" within the meaning of FIFRA.

Further, Behnke contends there is a disputed issue of fact whether its Lubricants mitigate "pests" within the meaning of FIFRA due to their usage only in food and beverage plants and are claimed, therefore, to be relevant only as to organisms "*on or in processed* food or processed animal feed, beverages, drugs, and cosmetics " so as to exempt them from the definition of "pests" and, therefore, "pesticide" subject to FIFRA registration.

Finally, (as further articulated below) Behnke's defenses may be relevant to the "gravity" assessment penalty. *See In the Matter of Dearborn Refining Co.*, Docket No. RCRA-05-2001-0019, 2003 EPA LEXIS 10, at *6 (ALJ, January 3, 2003).

EPA cites a number of sources (including extensive congressional history, committee reports, EPA reports, Federal Register Notices, the FQPA, the FFDCA, etc.) outside the pleadings which remove this argument from the confines of a Motion to Dismiss. "Affirmative Defenses should only be stricken when they are insufficient on the face of the pleadings." *Martell*, 844 F. Supp. at 457. For this reason alone, EPA's motion must fail.

With regard to Aff. Def. 3 alone, EPA provides seven pages of detailed legislative history and citation to outside sources; plus ten more pages following regarding the other defenses. It is, therefore, patently clear that the sufficiency of Behnke's Affirmative Defenses 3-6 must be fully tested with the benefit of a fuller record, e.g., on a motion for summary judgment if not a full hearing. *See Martell, Id.* In sum, EPA's arguments well exceed the confines of Motion to Dismiss.

EPA has failed to meet its high burden of showing the legal and factual insufficiency of Behnke's Affirmative Defenses 3-6 (if they are even, in fact, affirmative defenses at all); that any prejudice or confusion will result from such defenses; or that there is no set of circumstances under which the defenses could succeed at trial. Therefore, EPA's motion fails or, at a minimum, the issue regarding the legal sufficiency of Behnke's defenses as to liability in this matter is better left and should be left for the Court's consideration on Complainant's Motion for Accelerated Decision.

At this stage, granting a Motion to Strike would be premature and unnecessary. Whether any of these defenses can serve as a bar to Behnke's liability can be better addressed in Behnke's response to Complainant's Motion for Accelerated Decision. *See In the Matter of Scotts-Sierra Crop Protection Co.*, Docket No. FIFRA-09-0864-C-95-03, 1996 EPA ALJ LEXIS 138, at *5 (ALJ, August 19, 1996). For these reasons, Complainant's Motion to Dismiss Affirmative Defenses Nos. 3, 4, 5 and 6 must be denied, or in the alternative, deferred pending the outcome of EPA's Motion for Accelerated Decision.

BEHNKE HAS COMPLIED WITH ALL ORDERS AND REQUISITE DISCLOSURES

EPA also moves for discovery in connection with Behnke's Affirmative Defenses 1, 2, 5 and 6. (Motion to Strike, p. 30).

Until now, EPA (although invited to do so) has failed to request formal discovery in compliance with 40 CFR §22.19(e). Behnke has at all times complied with the Court's Order dated June 27, 2007, and the Consolidated Rules of Procedure and cooperated with Complainant to the extent reasonably possible.

In accordance with the June 27, 2007 Order, Behnke timely filed its initial prehearing information exchange on or about November 13, 2007 which disclosed 14 fact witnesses and 3

expert witnesses. (Respondent's Prehearing Exchange). It also disclosed 59 multi-page exhibits it intends to introduce into evidence at hearing in support of its ultimate defense that Behnke's Lubricants are not "pesticides" within the meaning of FIFRA. Most of the evidence produced goes directly to the factual issue of the "intended use" of the Lubricants to show that they are 1) primarily used for lubrication of machinery in the food and beverage processing industry; and 2) are likely in their intended use to come into contact with, and become a part of, processed foods and beverages.

Early on in this proceeding, on or about June 19, 2007 Complainant served and filed an eight page "Notice of Complainant's Request for Voluntary Production of Financial Information" relative to Behnke's "ability to pay" the penalty proposed in the Complaint. In July of 2007 Complainant filed a similar notice relative to the "ability to pay" issue. At this point, no presiding officer had been assigned to preside over the case.

In its Initial Prehearing Exchange Behnke expressly conceded it had the ability to pay the proposed civil penalty. For this reason, both requests for voluntary disclosure of financial information were rendered moot.

On or about June 22, 2007 Complainant served and filed yet another 8 page Notice of Request for Voluntary Production of Information this time requesting the voluntary production of numerous details and documentation purportedly relating to Behnke's affirmative defenses, including documents and communications relating to Behnke's products with the FDA, DHHS, OPP, NSF, among others. An original copy of this request is on file with the Court. In the nature of interrogatories, the notice also asked Behnke to "specify" and "clarify" dozens of details involving the Lubricants. This Court need only review the Notice to see that it is

overreaching and a response would have been costly and time-consuming for Behnke to prepare to the extent requested by EPA.

After the information exchange a party can move for additional discovery. §22.19(e). Behnke filed its Initial Prehearing Exchange on or about November 13, 2007. Only after more than two months passed and the Court filed its Order on January 14, 2008 setting the matter for hearing beginning March 31, 2008 did EPA file its extensive Motion to Dismiss and Motion to Compel and, shortly thereafter, its extensive Motion for Accelerated Decision.

This Court should not compel Behnke to comply with overly broad and burdensome discovery requests that were never formally authorized in accordance with the Rules in the first instance. At most, the Court can only consider EPA's request for an Order allowing additional discovery and only then if it determines EPA meets the three requirements for additional discovery:

> (e) Other discovery. (1) After the information exchange provided for in paragraph (a) of this section, a party may move for additional discovery. The motion shall specify the method of discovery sought, provide the proposed discovery instruments, and describe in detail the nature of the information and/or documents sought (and, where relevant, the proposed time and place where discovery would be conducted). The Presiding Officer may order such other discovery *only if* it:
>
> (i) Will neither unreasonably delay the proceeding nor unreasonably burden the non-moving party;
>
> (ii) Seeks information that is most reasonably obtained form 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.

40 CFR §22.19(e)(emphasis added).

Although not articulated as such, it appears EPA's request for discovery is in the nature of interrogatories and requests for production of documents. The specific requests are described in a proposed "Order on Discovery" accompanying its motion. Including its subparts, the requests are at least 46 in number and involve numerous products and governmental agencies and EPA desires a response before March 3, 2008; which is at or about the same time Behnke will be charged with preparing a response to EPA's 62-page Motion for Accelerated Decision and 26-pages of affidavits.

Most federal courts provide limits on the amount of additional discovery that can be requested of other parties. If EPA were in a federal court, its requests would be rejected based on pure number alone. *See, e.g.,* United States District Court for the Eastern District of Wisconsin Civil L.R. 33.1 (limiting written interrogatories to 25 including subparts).

Behnke disclosed all its witnesses and exhibits to EPA well in advance of hearing. Apparently ignored by EPA, much of the evidence that will be used to support Behnke's defenses in this matter will be in the form of oral testimony. There is no requirement that Behnke produce "substantial evidence" to support its defenses in the prehearing exchange. (Motion to Dismiss, p. 32). This is a meritless argument. EPA cites case law as support which addresses the production of evidence in the confines of motions for accelerated decisions, not motions for other discovery or the standard for prehearing disclosures and are, therefore, inapplicable here.

EPA claims Behnke "failed to submit any of the information pertaining to its affirmative defenses in its prehearing." That is false; Behnke's defenses will be presented by testimonial evidence of witnesses identified in its initial prehearing exchange as well as the documents already disclosed to EPA. Further, EPA has been in communication with Behnke's counsel prior

to the commencement of a civil action; in fact, the parties had a person-to-person meeting at the EPA's office in Chicago. Complainant is well aware of the basis for Behnke' affirmative defenses and the belief that its products are subject to FDA regulation, *not* EPA regulation. Behnke does not contend one statutory scheme "trumps" the other. Rather, Behnke's primary intent is to show the Court that Congress did not intend two federal agencies to regulate the use of the same products within the context of the food processing industry. The EPA recognized this Congressional intent in 1999:

> 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).

Behnke also strongly disagrees with EPA's contention that granting their request for additional discovery will not "unreasonably delay the proceeding" or "unreasonably burden Respondent." (Motion to Dismiss, p. 34). The information requested is very comprehensive, overbroad, and burdensome for Behnke to produce and, arguably, most is irrelevant to this proceeding. Much time and expense would be expended by Behnke in preparing responses at a

time when EPA has filed dispositive motions exceeding 100 pages in length and less than two months prior to hearing. Further, EPA continues to submit additional witnesses and exhibits for use at trial well past the prehearing information exchange schedule.

Allowing sufficient time for the Court to consider the request and render a decision while providing Behnke with sufficient time to response to the requests while requiring it to fully respond to the extensive Motion for Accelerated Decision will prejudice Behnke and may necessitate a postponement which Behnke seeks to avoid. Moreover, much of the information is "otherwise obtainable" either through the individual agencies involved or through cross-examination of Behnke's witnesses at hearing. *See In the Matter of International Paper Com.*, Docket No. CAA-R6-P-9-LA-98030, 2000 EPA ALJ LEXIS 40, at *8 (ALJ, January 26, 2000). Therefore, EPA's claim that the information cannot be obtained from any other source is without merit.

EPA spends 35-pages discussing why it contends the discovery order should be issued. However, this Court need only look to the substance of the requests to determine they are not reasonable and will unreasonably burden Behnke, particularly at this late date in the proceedings. Much of it is in the nature of "fishing expeditions" and otherwise available to EPA through third-party sources.

Behnke understands that the introduction of documents at hearing not included its prehearing exchange will not be allowed. EPA, therefore, has everything in its possession Behnke believes at the present time will support its case including exhibits and witness identities. As in *International Paper*, this proceeding is better served by EPA inquiring into specific matters of interest by cross-examination at hearing.

Although not stated as such, some of EPA's requests essentially inquiries into the minds and strategy of its counsel as to how it will prove Behnke's defense to the Complaint at hearing. However, Fed. R. Civ. P. 26(b)(3) protects the mental impressions, conclusions, opinions, or legal theories of an attorney concerning the litigation (commonly known as "attorney-work product") and should not be allowed here as well.

Similar to Fed. R. Civ. P. 26(a), the initial prehearing disclosures required under Rule 22.19(a) include the identity of lay and expert witnesses and copies of documents that a party may be used to support its claims or defenses. The EPA cannot state Behnke's defenses are unsupported when it has not yet heard the testimony of Behnke's witnesses. Much of the information EPA seeks can either be obtained from third-party agencies or by cross-examination of Behnke's witnesses. There is no requirement that EPA know every detail of Behnke's case or the testimony of its witnesses, rather only the proper initial disclosures must be made (and have been made here). EPA must satisfy the three criteria for "other discovery" which it cannot meet with regard to the 46 plus requests sought in the present motion.

Finally, EPA criticizes nearly every aspect of Behnke's witness disclosures and summaries. There is no requirement that Behnke's disclosures provide the detail desired or requested. Again, this information can be elicited by cross-examination at hearing; there is no specific need for this information prior to the hearing. Behnke does note, however, that had the EPA requested additional pre-hearing discovery of Behnke's witnesses before this late date, depositions on oral examination would have expeditiously satisfied EPA's supposed needs. We can only conjecture that should more specific witness information be provided to EPA, it will then likely object at hearing if Behnke failed to disclose every single word of anticipated testimony.

In essence, EPA would like to try this case on paper. However, Behnke is entitled to trial on any disputed issue of fact and this Court should not allow EPA to otherwise burden Behnke with unnecessary and unwarranted discovery without "significant probative value" to a full and fair hearing on the issues ultimately presented in this case, particularly at this late date and while a Motion for Accelerated Decision is pending.

Clearly, the Complainant has many more resources and personnel available to seek this information, if, in fact, it really needs it. Much of the information would be readily available to Complainant by the filing of a Freedom of Information Act request with the applicable government authority or communicating directly with the authority. Interestingly, one request even relates to documents and communications with the U.S. EPA!

For these reasons, Behnke respectfully requests that the Court deny EPA's request for additional discovery or, in the alternative, limit discovery at this late date to very narrow, specific requests that will not unreasonably delay this proceeding or overburden Behnke in light of the pending hearing and extensive Motion for Accelerated Decision, and to information that has significant probative value and is not otherwise obtainable from other sources.

BEHNKE'S POSITION ON THE PROPOSED PENALTY

In its prehearing exchange, Behnke specifically waived any objected to the civil penalties proposed in the Complaint based on its inability to pay or the effect of the penalty on Behnke's ability to continue in business. Behnke specifically admitted it would be able to pay the proposed penalty and the penalty would not have an adverse effect on its ability to continue to do business. While not expressly stated, by implication, it is Behnke's intention to challenge the remaining factor in Complainant's calculation of a proposed penalty; namely, "gravity of harm."

Section 14(a) of FIFRA, 7 USC §136l(a), provides the statutory criteria for calculating

civil penalties for FIFRA violations. According to Complainant's FIFRA Civil Penalty Calculation Worksheet in this matter (CX 14), it has an assigned a "Total Gravity Value Adjustment Value" of 5 to Behnke's purported violations, including a "2" Culpability value . Adding this to the other penalty calculation factors, EPA reduced the Base Penalty by 30%.

Behnke takes issue with the "2" culpability level assigned by Complainant and maintains it should have been assigned a "O" culpability level. According to Complainant's documents, "culpability" was assigned a value of two "based on unknown culpability of the Behnke with respect to these violations." (CXA 14b: EPA 0344).

A "Level 2" culpability value is placed for "violation resulting from negligence" or "culpability unknown." A "Level 0" culpability, on the other hand, is assigned when "violation was neither knowing nor willful and did not result from negligence." As Behnke does not believe in the first instance its products constitute "pesticides" regulated under the Act, by implication any violation cannot be said to be knowing or willful or result from negligence. Under Complainant's position, ANY violation would automatically result in at least the assignment of a "Level 2" factor.

A Total Gravity Value of 3 or below the enforcement remedy is no action, a Notice of Warning or a 50% reduction of matrix value. Under Complainant's assessment of culpability, a Total Gravity Level of 5 resulting in a reduction matrix value of 30 %. The difference between EPA's culpability assessment and Behnke's is a $3,250 vs. $4550/Count penalty or a total of $35,750 vs. $50,050. Complainant assigned a weighting factor of 2 (culpability unknown) at the time the complaint was issued without consideration of the facts in this case and Behnke will argue, based on the testimony of its witnesses that any violations were neither "knowing nor

willful" or resulting from "negligence," but were based on a good faith belief that its products were not "pesticides" within the meaning of FIFRA.

CONCLUSION

For these reasons and the reasons stated herein, Behnke respectfully request that Complainant's Motion to Strike Respondent's Affirmative Defenses, and Complainant's Motion to Compel Discovery be denied.

Dated: February 4, 2008.

McIlnay & Button, Ltd.
Counsel for Behnke

By: _____
Bruce A. McIlnay
Linda S. Isnard

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

CERTICATE OF SERVICE

The undersigned hereby certifies that he has caused a true and correct copy of foregoing RESPONSE TO COMPLAINANT'S MOTION TO STRIKE RESONDENT'S AFFIRMATIVE DEFENSES AND MOTION TO COMEL DISCOVERY to be served upon the following on the date indicated below by overnight mail:

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

Dated: February 4, 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.

DECLARATION OF BRUCE A. McILNAY

STATE OF WISCONSIN)
) ss.
OZAUKEE COUNTY)

Bruce A. McIlnay, being first duly sworn, on oath deposes and says:

1. I am an attorney licensed to practice law in the State of Wisconsin and a member of McIlnay & Button, Ltd., which firm is legal counsel for the respondent, Behnke Lubricants, Inc., in the above-captioned matter.

2. I make this declaration of my own personal knowledge.

3. Attached hereto as Exhibit A is a true and correct copy of a letter from the Honorable F. James Sensenbrenner, Jr. enclosing a copy of a letter addressed to Representative Sensenbrenner from Ms. Mary Gade, Regional Administrator, Region 5, United States Environmental Protection Agency, dated February 1, 2007.

4. In this letter, Ms. Gade avoids the question of whether the "Lubricants" at issue in this matter are antimicrobial pesticides within the meaning of 7 U.S.C. §136(mm). Rather she states that is the EPA's position that the lubricants fall under the definition of "pesticides" in Section 2(u) of FIFRA, 7 U.S.C. §136(u). Ms. Gade further states that the reason for inclusion is that the respondent's labels make claims concerning control of

micro-organisms. She further states that the definition of "pests" in Section 2(s) of FIFRA, 7 U.S.C. §136(s), includes bacteria or other micro-organisms. She goes on to say that "FIFRA regulations at 40 C.F.R. 152.15(a)(1) further states that a substance is a pesticide requiring registration if a person who distributes or sells the substance claims, states or implies, by labeling or otherwise, that the substance can or should be used as a pesticide."

5. Ms. Gade fails to address, however, that the same regulations she cites exclude any "fungus, bacterium, fungus or other micro-organism" if it is "on or in living man or other living animals" and those "on or in processed food or processed animal feed, beverages, drugs and cosmetics." *See,* 40 C.F.R. §152.5(d).

Bruce A. McIlnay

Subscribed and sworn before me
this 4th day of February, 2008.

Notary Public, State of Wisconsin
My commission expires: 6-28-2009

F. JAMES SENSENBRENNER, JR.
FIFTH DISTRICT, WISCONSIN

COMMITTEE ON THE JUDICIARY
CHAIRMAN

WASHINGTON OFFICE:
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RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-4905
202-225-5101

DISTRICT OFFICE:
120 BISHOPS WAY, ROOM 154
BROOKFIELD, WI 53005-6294
262-784-1111

OUTSIDE MILWAUKEE METRO
CALLING AREA
1-800-242-1119

Congress of the United States
House of Representatives
Washington, DC 20515–4905

February 9, 2007

Mr. Eric Peter
Behnke Lubricants, Inc.
W134 N5373 Campbell Drive
Menomonee Falls, WI 53051

Dear Mr. Peter:

In response to your inquiry regarding the U.S Environmental Protection Agency's (EPA) Notice of Intent to File a Civil Administrative Complaint against Behnke Lubricants, Inc., I am enclosing a copy of the reply I recently received from the EPA.

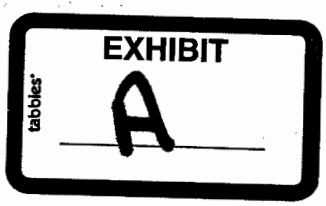
I am hopeful the comprehensive response is helpful to your concerns. Should you have any questions regarding this response, please contact my district office at (262) 784-1111.

If I may ever be of service in the future, do not hesitate to contact either my Washington Office or District Office in Wisconsin. In any event, continue to keep me informed of your views on issues and concerns.

Sincerely,

F. JAMES SENSENBRENNER, JR.
Member of Congress

FJS:bas
Enclosure



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

FEB - 1 2007

REPLY TO THE ATTENTION OF:
R-19J

Honorable F. James Sensenbrenner, Jr.
Member, U.S. House of Representatives
120 Bishops Way, #154
Brookfield, Wisconsin 53005

Dear Congressman Sensenbrenner:

Thank you for your letter dated January 22, 2007, on behalf of Mr. Eric Peter of Behnke Lubricants, Inc. in Menomonee Falls, Wisconsin, which referenced our December 22, 2006 Notice of Intent to File a Civil Administrative Complaint against Behnke Lubricants for the sale and distribution of the unregistered pesticides, 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. Attached to your letter was a memorandum from Mr. Peter and his attorney, Mr. Bruce McIlnay, in which they question the inclusion of the Behnke Lubricants products listed above within the Federal Insecticide, Fungicide and Rodenticide (FIFRA) definition of "antimicrobial pesticides," 7 U.S.C. § 136(mm). Your letter asked us to review Mr. Peter's concerns and to address which portion of FIFRA gives the U.S. EPA regulatory authority over the Behnke Lubricants' products mentioned above.

Behnke Lubricants' products fall under the definition of "pesticides" in Section 2(u) of FIFRA, 7 U.S.C. § 136(u), because the company, in its advertising and on its labels, makes claims concerning control of micro-organisms relating to each product. The definition of "pest" in Section 2(s) of FIFRA, 7 U.S.C. § 136(s), includes bacteria or other micro-organisms. A pesticide is any substance or mixture of substances that is intended to prevent, destroy, repel or mitigate any organism that fits the FIFRA definition of pest. FIFRA regulations at 40 C.F.R. § 152.15(a)(1) further state that a substance is a pesticide requiring registration if a person who distributes or sells the substance claims, states or implies, by labeling or otherwise, that the substance can or should be used as a pesticide.

The definition of "antimicrobial pesticides," referenced in Mr. Peter's memorandum, is a subset of the definition of "pesticide." The definition of "antimicrobial pesticides" was added to FIFRA to allow for an expedited review process for the registration of subject antimicrobial pesticides. It was not intended to exclude any class of pesticides from registration. This revised review period is further referenced in Section 3(h) of FIFRA, Registration Requirements for Antimicrobial Pesticides, 7 U.S.C. § 136a(h). Regulations for implementation of this revised registration process, proposed in the September 17, 1999 Federal Register, have not yet become final. To date the U.S. EPA has insufficient information from Behnke Lubricants to determine if their products are "antimicrobial pesticides," but my staff is currently engaged in discussions with your constituents to review this and other issues. Regardless of whether the Behnke

Lubricants' products fall under the narrow definition of "antimicrobial pesticides," they are pesticides under the much broader definition of "pesticides" and are subject to FIFRA.

Again, thank you for your letter. If you have further questions, please contact me or your staff may contact Mary Canavan or Phil Hoffman, the Region 5 Congressional Liaisons, at 312-886-3000.

Sincerely,

Mary A. Gade
Regional Administrator