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July 16, 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 Reply Brief with respect to the above-referenced matter.

The original and one copy of Respondent's Reply Brief were delivered to the Regional Hearing Clerk, Region 5, U.S. EPA via messenger on July 16, 2008. A true and accurate copy of same was delivered to Nidhi O'Meara via messenger on July 16, 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

Regional Hearing Clerk, w/encls. (via messenger)

Nidhi O'Meara, w/encls. (via messenger)

Eric Peter, w/encls.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 5

In the Matter of:

BEHNKE LUBRICANTS, INC. MENOMONEE FALLS, WISCONSIN

Docket No. FIFRA-05-2007-0035

Respondent.

RESPONDENT'S REPLY BRIEF

INTRODUCTION

Respondent Behnke Lubricants, Inc. ("Behnke" or "Respondent") respectfully submits this Reply Brief in the above-captioned matter pursuant to the Court's Order dated May 1, 2008 and Section 22.26 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/ Termination or Suspension of Permits (the "Rules of Practice"), 40 C.F.R. § 22.26.

ARGUMENT

I. BEHNKE'S LUBRICANTS ARE NOT "PESTICIDES" WITHIN THE MEANING OF FIFRA.

A. BEHNKE OFFERED OVERWHELMING EVIDENCE THAT THE LUBRICANTS AT ISSUE TARGETED MICROBES "ON OR IN PROCESSED FOODS" AND THEREFORE ARE EXEMPT UNDER 40 C.F.R. §152.5.

Contrary to Complainant's assertions, a review of the evidence here reveals substantial documentary and testimonial evidence to support Behnke's assertion that the Lubricants target microbes "on or in processed foods" and, therefore, by definition, are not "pesticides" within the meaning of FIFRA. Namely, Behnke's evidence -- consisting of testimony from the Lubricants' designers, marketers, and customers – demonstrates that beginning with the evolution of these products and ending with their use in the field, the Lubricants' Micronox component sought to

control microbes "on or in processed foods." Simply put, Behnke offered uncontested evidence that its intent with respect to the promotion of Micronox in the Lubricants was to control microbes "on or in processed foods."

1. Behnke's intent in designing Lubricants with antimicrobial properties was to provide its customers with a lubricant that could control antimicrobials "on or in processed food."

Behnke's witnesses, Mr. Eric Peter and Mr. Troy Paquette, testified that the origins behind Behnke's development of the antimicrobial line of Lubricants at issue stemmed from the request of one of its customers (i.e. Kraft) for an industrial lubricant with secondary antimicrobial properties. (Tr. 589-91, 777-78). The record establishes that Behnke worked closely with Kraft to address Kraft's concerns that one of its ball bearings was transferring unacceptable microbes into its processed foods. (Tr. 590-91). The record further demonstrates that Behnke worked hand-in-hand with Kraft to monitor the on-going success of the new lubricant in controlling the microbes on and in the processed food at issue. (Tr. 588-90). The record also shows that Kraft purchased Behnke's line of Lubricants following this extensive testing phase. (Tr. 589).

The record demonstrates that Behnke continued to build on its new lubricant's success in controlling microbes "on or in processed foods" as the company created its antimicrobial line of Lubricants, five of which are the focus of this proceeding. (Tr. 590, 594-95). Behnke respectfully submits that it has shown that Behnke never intended the Lubricants to target microbes in general, but only those of concern when the Lubricants became an incidental part of the processed foods or beverages.

2. Behnke's customers understood that the Lubricants frequently came into contact with their processed food and beverage articles.

Behnke's Lubricants are sold to a food and beverage industry that has considerable experience with the interaction between the Lubricants and the food or beverage articles in their plants. In this regard, Behnke presented evidence that Behnke's major customers, companies like Kraft and Quaker Oats, invest considerable attention and resources in addressing incidents of contact between their Lubricants and food products. (Tr. 778-81, 821, 828-29, 830-35). Even Complainant's own witness, Mr. Rybicki, testified that his company has a formal protocol for dealing with incidents of contact between the Lubricants and the food articles in the American Foods Group plant. (Tr. 119).

Simply stated, Behnke's customers know that the Lubricants used in their plants will inevitably come into contact with their food or beverage articles. The record shows that Behnke anticipated its customers' institutional knowledge regarding the likelihood of contact between Lubricants and processed food and beverage articles, and Behnke used this knowledge to build its competitive advantage in marketing an antimicrobial line of Lubricants that could control microbes "on or in processed foods." (Tr. 600). Indeed, Behnke offered testimony that multiple customers approached Behnke regarding their desire to use an antimicrobial lubricant to control microbes "on or in processed foods." (Tr. 589-91, 777-78, 885-890).

3. Behnke's customers recognize that they are unable to detect every incident of contact between a food item and lubricant.

Behnke offered the following uncontested evidence at hearing:

The origin of Behnke's line of antimicrobial Lubricants stemmed from Kraft's request for a lubricant possessing antimicrobial properties that could assist Kraft in controlling the microbes on and in its processed cheese. (Tr. 589-91, 777-78).

Behnke received requests from two national companies after lubricants used in their plants contaminated their food products and, ultimately, were sold to the consumer. On one such occasion, a customer of one of these companies actually became quite ill after ingesting a lubricant-contaminated food product. (Tr. 885-889).

Behnke received, and continues to receive, inquiries from customers concerned about contact between their food product and the Lubricants. (Tr. 873-74).

Behnke's expert, Mr. Cooper, testified that in his decades of experience with Quaker Oats and in the food industry as a consultant, he has frequently addressed concerns arising from incidents of contact between industrial lubricants and food products. (Tr. 833-34, 847-49). Mr. Cooper stated that despite his best efforts and considerable experience, he was unable to detect every incident of contact between a lubricant and food product. (Tr. 834). Mr. Cooper further stated that he knew of at least one incident where a food product contaminated by a lubricant reached the ultimate consumer. (Tr. 844). Finally, Mr. Cooper testified that Quaker Oats and a client of his consulting firm purchased Behnke's antimicrobial line of lubricants, in part, because of their desire to target microbes "on or in processed foods." (Tr. 842-43, 848-49).

To counter Behnke's position, Complainant rests on the testimony of Mr. Rybicki that his company has a formal protocol for checking meat carcasses that come into contact with lubricants. (Compl. Br., p. 42). Complainant relies on Mr. Rybicki's testimony, as well as snapshots of Mr. Cooper's and Mr. Peter's testimony, to support its flawed premise that because Behnke's Lubricants are not specifically intended to become a part of the processed food, Behnke's Lubricants cannot intend to target pests "on or in processed foods." (*Id.* at 39-42). In so doing, Complainant ignores the uncontested evidentiary record here that although Behnke's Lubricants may not be specifically designed to become a part of the processed food, the reality is

that contact between the Lubricants and processed foods is an unavoidable and expected part of the lubricating process. Even Mr. Edwards acknowledged that he did not know whether food processors could detect every incident of contact between a lubricant and a food or beverage article: "Do I know whether or not that the processors capture any and all lubricant that might inadvertently drop onto the carcasses? No." (Tr. at 377).

The record shows that while Behnke does not intend for its Lubricants to become an identified ingredient of its customers food products, Behnke does intend for its Lubricants to target antimicrobials "on or in" the product when such contact unavoidably occurs.

4. Behnke sells its products to a sophisticated and experienced food and beverage industry.

Behnke offered substantial and uncontested evidence that its products are sold to the food and beverage industry and that Behnke's customer base consists of sophisticated and experienced purchasers. Specifically, Behnke offered evidence – by way of testimony of its president, Mr. Peter — that its food grade lubricant customers derive exclusively from the food and beverage industry. (Tr. 570). Behnke supported this evidence with product information that demonstrated the unique properties and price points of the Lubricants at issue in this case, attributes that limit the market for these Lubricants to the food and beverage industry. (Tr. 570-71, 578, 580-82). Additionally, Behnke offered evidence that its relationship with customers includes an extended sales cycle and intensive customer interaction that customizes a product package based on individual customer needs. (Tr. 878-881). The evidence of Behnke's actual business practices, as well as evidence of Behnke's actual sales history demonstrates that Behnke intended the five Lubricants at issue in this case to be sold exclusively to the food and beverage industry.

By contrast, Complainant offered a series of "what-if" scenarios based on hypothetical and questionable premises that are not relevant to Behnke's intent in selling the five Lubricants at issue in this case to customers within the food and beverage industry. (Compl. Br. at 48-51).

The record is devoid of any evidence that the Lubricants were sold to anyone outside of the food and beverage industry or that these Lubricants were used in any manner inconsistent with Behnke's recommended use. Behnke's business practices and sales history clearly demonstrate that the five Lubricants were exclusively intended for the food and beverage industry.

To place Behnke's position in context, the record evidences that Behnke's customers are sophisticated purchasers of food-grade lubricants who possess a long history of experience with Behnke and the United States Food and Drug Administration ("FDA"). The evolution of Behnke's own product line demonstrates the sophistication and experience of the food and beverage industry with respect to the use of the Lubricants in their plants.

Eric Peter, Behnke's president, testified to his company's forty-year history with food grade lubricants, starting with a simple lubricant formula to the present state of affairs based on extensive FDA oversight of food grade lubricants. (Tr. 561-67). Mr. Paquette testified that Kraft approached Behnke after extensive testing on one of Kraft's ball-bearings revealed that the bearing was transferring microbes to some of Kraft's food products. (Tr. 778). Further, Mr. Cooper testified to the extensive procedures Quaker Oats employed to ensure compliance with the FDA regulations. (Tr. 828-35). These FDA regulations contain extensive procedures — authorized in FFDRA — to ensure that same Lubricants at issue in this case are safe for their intended use and not deleterious to consumers. (Tr. 560-63). In sum, the record contains substantial evidence that the food and beverage industry consists of experienced and

sophisticated customers who ensure the safety of their products through compliance with the governing FDA regulatory regime.

Curiously, Complainant appears to challenge Behnke's position that the food and beverage industry consists of sophisticated and experienced industry participants. (Compl. Br. at 85). Specifically, Complainant seeks to impute evidence that one industry participant used WD-40 in a food-processing plant onto the entire food and beverage industry. *Id.* For this reason, Complainant infers from its own hypothesis that the entire food and beverage industry requires EPA oversight of Lubricants possessing antimicrobial properties. *Id.*

Complainant's broad conclusion in this regard belies common sense and dictates a noneconomical and impractical approach to global food safety. Complainant's argument fails to controvert the evidentiary record supporting Behnke's position that the food and beverage industry requires companies to utilize their experience and knowledge in order to remain competitive. (Tr. 563-65, 569, 575, 870-71).

B. THE "REASONABLE CONSUMER" OBJECTIVE STANDARD IS THE APPROPRIATE FRAMEWORK FOR ANALYZING BEHNKE'S LABELING CLAIMS.

The appropriate framework for analyzing the Behnke's claims is within the "reasonable consumer" objective standard as adopted by the court *In the Matter of Caltech Industries*, Docket No.5-IFFRA-97-006. In *Caltech*, the court stated that "[w]hether a product is a pesticide, is to be determined by all claims made for the product on labels or otherwise, <u>and</u> the intent of the use, if the seller distributor has actual or constructive knowledge of the intent of the user." (citing N. Jonas v. U.S. EPA, 666 F.2d 829 (3rd Cir. 1981)(emphasis added). Caltech clarified that the

¹ It should be noted that even this one customer was looking for a better solution and hired Mr. Cooper, who does possess significant sophistication in the food processing industry to address its concerns. (Tr. 847-89).

"reasonable consumer" standard is understood in terms of the relevant market for a particular product, in this case the food and beverage industry.

Though Complainant's post-hearing brief does not address this issue, the Court cannot and should not analyze Complainant's allegations in the vacuum it promotes here. Ultimately, Complainant's allegations hinge on the effect the language in Behnke's brochures and labels had on its customers' understanding of the purpose behind Behnke's labeling claims. As a result, Complainant's allegations are meritless if Behnke's customers were not affected by Behnke's word choice in its brochures and labels, despite the EPA's dissection of isolated words and phrases in Behnke's literature from the viewpoint of third-parties who lack the experience and perspective that defines Behnke's relationships with its customers.

1. A reasonable consumer in the food and beverage industry would not interpret Behnke's labeling as advocating its Lubricants use as a pesticide.

Analyzed within the required "reasonable consumer" objective standard Complainant's allegations take on an entirely new meaning. Specifically, the basis for Complainant's case rests on the claim that 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 a pesticide." *See* 40 CFR 152.15(a)(1). In so doing, Complainant fails to consider these isolated words or phrases from the perspective of a reasonable consumer in the food and beverage industry.

According to Complainant's argument, Behnke has spent years misleading its consumers into believing its Lubricants helped to preserve the Lubricant or the machinery behind the Lubricant. To this end, Complainant appears to argue that Behnke's management only recently began to claim that its Lubricants have any affect on food and beverage articles in order to justify Behnke's position in Court. (Br. at 68, 106).

The truth regarding Behnke's line of antimicrobial Lubricants is evident in the record: Beginning with Kraft Foods, Behnke intended its line of antimicrobial lubricants to target microbes "on or in processed foods." (Tr. 778, 808-09). Behnke admits that isolated sections of particular brochures or labels contained claims inconsistent with the true purpose of Behnke's antimicrobial lubricants. However, the record contains ample evidence that Behnke's customers were fully aware that the antimicrobials in Behnke's Lubricants were intended to target microbes "on or in processed foods." (Tr. 589-91, 782, 841-44, 885-90). Behnke offered testimony regarding three of its largest customers requesting assistance in addressing problems with microbes "on or in processed foods." (Tr. 885-90). Additionally, Behnke offered the testimony of Mr. Cooper, who indicated that he personally purchased JAX Halo-Guard for Quaker Oats in an effort to address bacteria problems stemming from incidental food contact incidents. (Tr. at 841-44).

There is no credible evidence that Behnke's customers understood that the Lubricants in question were to be used as pesticides. Complainant apparently relies on the testimony of Mr. Rybicki for the proposition that American Foods Group foods did not understand that Behnke's Lubricants were intended to target microbes "on or in processed foods." (Br. at 44). However, the evidentiary value of this evidence is questionable as Mr. Rybicki testified that he did not make the purchasing decisions at American Foods Group and was not aware of what motivated the individual actually responsible for purchasing Behnke's Lubricants. (Tr. 99). Additionally, while Complainant's other witnesses offered substantial testimony as to how they internally perceived the claims in Behnke's literature, none of these witnesses testified from the single

² It is telling that Complainant did not offer the testimony of the person, Dr. Mohseni, who Mr. Rybicki identified as making the decision to purchase the Lubricants. (Tr. 99).

perspective that mattered: the perspective of a reasonable consumer in the food and beverage industry.

To this end, Mr. Rybicki admitted in his testimony that he lacked the authority to purchase Lubricants for American Foods Group, undermining the relevance of his testimony in this regard. (Tr. 99).

The record contains at least a preponderance of evidence in Behnke's favor that a reasonable consumer in the food and beverage industry understands that the Lubricants target microbes "on or in processed foods." To support its position regarding the mindset of a "reasonable consumer" in the food and beverage industry it targets, Behnke offered: (1) evidence regarding its actual business practices of competitively selling its Lubricants as uniquely targeted to microbes "on or in processed foods;" (2) the history of the Lubricants as expressly designed to target microbes "on or in processed foods;" (3) the history of three of its customers who requested Behnke's Lubricants to target microbes "on or in processed foods;" (4) an outside expert who testified to Quaker Oats' usage of the Lubricants to target microbes "on or in processed food;" and (5) Mr. Cooper's experience as a consultant with other members of the food and beverage industry who purchased Behnke's Lubricants to target microbes "on or in processed foods."

To counter Behnke's evidence in this regard, Complainant offered: (1) Mr. Rybicki, a single employee from one customer who lacked the authority to choose among competing lubricants; and (2) testimony from the perspective of self-interested government employees as to what they understood Behnke's labels and brochures as advocating. Behnke submits that Complainant offered no evidence regarding the mindset of a "reasonable consumer" in the food and beverage industry.

Similarly, the basis for much of the EPA's testimony regarding objectionable language in Behnke's promotional literature stems from language derived from Behnke's discussions with NSF and EPA. For example, Behnke inserted isolated language in its brochures indicating that the antimicrobials in its Lubricants could control decay in the lubricant itself. (Tr. 605). Mr. Peter testified to Behnke's reluctance to accept NSF's recommendations in this regard, which he believed (with good reason) came in part from the EPA, and that it was never Behnke's intent to lead its customers into believing that Behnke's antimicrobial line of Lubricants were intended to target anything but microbes "on or in processed foods." (Tr. 605). In this context, it is likely that the language objected to by Complainant had far more of an effect on the EPA and NSF than it did on any single consumer of the products. Indeed, common sense dictates that it would not have made a difference for customers like Kraft, Quaker Oats, or other multi-national customers whose names are included in the confidential portions of the court transcript, who had specific microbial problems "on or in processed foods." (Tr. 885-90)

II. BEHNKE DOES NOT MEET THE CRITERIA FOR AGGRAVATING FACTORS BASED ON THE GRAVITY OF THE VIOLATION OR THE POTENTIAL HARM TO THE PUBLIC.

Respondent notes at the outset of the penalty phase argument that much of Complainant's position rests on the assumption that Behnke must be punished for asserting its right to dispute the EPA's position from the outset and challenge the EPA in court. To this end, Complainant asserts, "Respondent has demonstrated a high degree of culpability, and a complete failure to exercise any care to correct the violations." (Br. at 118). In essence, Complainant seeks to hold Behnke ex-ante accountable for disputing Complainant's interpretation of an ambiguous law. Freedom to challenge our government is one of the basic tenants of our legal system and punishment should not be enhanced for exercising this fundamental right.

A. BEHNKE HAS ALWAYS SOLD PRODUCTS THAT COMPLY WITH FFDRA REGULATIONS FOR FOOD ADDITIVES.

Because Behnke has always sold its antimicrobial line of lubricants in compliance with FDA requirements under the FFDRA, Behnke respectfully submits that if any violation of FIFRA occurred, the potential harm to the public is nominal. While Complainant correctly notes that Behnke did not submit its products to EPA efficacy reviews, the record demonstrates that Behnke *did* submit its products for FDA review and approval. Indeed, the FDA approval requires that Behnke's products be safe for human consumption, FFDCA § 409, 21 U.S.C. § 348, while the EPA review focuses on the fitness of Behnke's products for targeting microbes that are not "on or in processed food." Section 2(t) of FIFRA, 40 C.F.R. 152.5(d).

Further, the record contains considerable evidence that Behnke and other third parties tested Behnke's antimicrobial line of lubricants to determine the efficacy of these products in targeting microbes "on or in processed foods." (Tr. 777-78). Since the record is devoid of evidence that Mr. Peter, or any other member of Behnke's management acted "in an almost willful manner," (Compl. Br. at 111), Respondent denies this assertion and notes its successful cooperation for more than forty years with governing regulatory authority. (Tr. 560-71).

B. BEHNKE INVESTED CONSIDERABLE TIME AND ATTENTION IN DETERMINING WHETHER ITS PRODUCTS REQUIRED EPA REGISTRATION; BEHNKE'S DECISION NOT TO SEEK EPA REGISTRATION BASED ON A GOOD FAITH BELIEF THAT THE REGISTRATION WAS NOT REQUIRED DOES NOT AFFECT THE GRAVITY OF THE VIOLATION.

Complainant's Post-Hearing Brief spends considerable time stressing that Behnke's management consistently made business decisions throughout the process leading up to this litigation. (Compl. Br. at 99-105). Complainant does not spend any time describing why Behnke's management should be held accountable for making business decisions.

As a result, it is unclear what alternative type of decision Complainant expected Behnke's management to make, or why Behnke's management is culpable for doing what it believed was in its company's best interests. Simply put, Behnke's management possessed a good faith belief — a belief that was reasonable enough to require a four day hearing to vindicate or discredit — that they were not required to register their product with the EPA. As a consequence, Complainant's conclusions regarding Behnke's culpability miss the mark. Namely, Complainant argues that Behnke: (1) missed red flags; (2) failed to know the true meaning of the word "label;" (3) failed to contact the EPA; (4) failed to bring a dossier of literature for the EPA's review when Mr. Peter did talk with the EPA; (5) marketed its line of antimicrobial lubricants; (6) avoided the inevitable; and (7) sought out the FDA's opinion. (Comp. Br. 90-106).

Complainant prefaces these arguments by accusing Behnke's management of "blatant disregard." (*Id.* at 91). The record, by contrast, shows that Behnke was not ignoring the inevitable or evading red flags. The record shows that Behnke was attempting to asserts its good-faith belief that the EPA's position – explained to Behnke through the EPA's chosen proxy NSF – was not correct, and that Behnke remained an FDA regulated entity. (Tr. 610-626).

Further, Behnke attempted to comply with the EPA and NSF recommendations to the best of its ability. (Tr. 599-610, 613-14, 624-626). It was only when Behnke believed that NSF and EPA's requests went too far that Behnke objected by asserting its legal rights. (Tr. 608-618). While Complainant concludes that "[Behnke's] behavior warrants a substantial penalty," (Compl. Br. at 107) Respondent respectfully submits that should the Court rule in Complainant's favor, Respondent should not be additionally punished for defending its good-faith interpretation of the law.

CONCLUSION

The record indicates that Behnke marketed the antimicrobial properties of its Lubricants for one simple purpose: to assist its customers in controlling microbes "on or in processed foods." To this end, Behnke used its on-going relationship with its sophisticated and experienced customer base to enable these customers to implement an antimicrobial line of Lubricants that could aid them in controlling microbes "on or in processed foods." The five Lubricants at issue in this case were sold first and foremost as lubricants and only secondarily with the intent that the antimicrobial properties of the Lubricants would target microbes "on or in processed foods." For this reason, Respondent respectfully requests that the Court dismiss Complainant's complaint on the merits.

Dated: July 16th, 2008.

McIlnay & Button, Ltd. Counsel for Behnke

By:

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that he has caused a true and correct copy of foregoing RESPONDENT'S REPLY 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) U.S. Environmental Protection Agency, Region 5 77 West Jackson Boulevard Chicago, IL 60604

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

Dated: July 1, 2008

Bruce A. McIlnay