UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	
	)	
BEHNKE LUBRICANTS, INC.	)	**COMPLAINANT'S REPLY TO**
MENOMONEE FALLS, WISCONSIN	)	**RESPONDENT'S RESPONSE TO**
	)	**COMPLAINANT'S MOTION**
	)	**FOR ACCELERATED**
	)	**DECISION ON LIABILITY**
	)	**AND ON AFFIRMATIVE**
	)	**DEFENSES**
	)	
	)	**Docket No. FIFRA-05-2007-0025**

COMPLAINANT'S REPLY TO RESPONDENT'S RESPONSE TO COMPLAINANT'S MOTION FOR ACCELERATED DECISION ON LIABILITY AND ON AFFIRMATIVE DEFENSES

Complainant, through its undersigned attorneys, files the instant Complainant's Reply to Respondent's Response to Complainant's Motion For Accelerated Decision on Liability and on Affirmative Defenses pursuant to the authority of Section 22.16(b) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits, ("Consolidated Rules" or "CROP") 40 C.F.R. § 22.16(b).

I. Respondent Fails to Recognize That the Controlling Statute is FIFRA, NOT FFDCA

On February 21, 2008, Behnke Lubricants, Inc. (Behnke or Respondent) filed its Response to Complainant's Motion For Accelerated Decision on Liability and on Affirmative Defenses (Response to MAD). In it, Behnke fails to recognize that the controlling statute and regulations in determining if it has violated the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is FIFRA and not the Federal Food,

Drug and Cosmetics Act (FFDCA). Behnke's response is filled with arguments and citations relating to the FFDCA which only serve to confuse the issue of whether the lubricants in questions are "pesticides" under FIFRA and its implementing regulations. As a result, all discussions regarding FFDCA are "red herrings" that only serve to lead Behnke and this Court down a road that is not relevant to resolving the FIFRA violations at hand. All FFDCA arguments must be disregarded as they are irrelevant and obfuscate the real issue at hand: if Behnke has violated FIFRA and its implementing regulations.

Behnke is incorrect in stating that *"the key to interpreting the ambiguity in FIFRA at the bottom of this case is whether the Lubricants are "food additives" regulated under FFDCA."* Response to MAD, at 14. First, the plain language of 40 CFR § 152.5(d)[1] in FIFRA's implementing regulations is clear on its face. Second, whether Behnke's lubricants are "food additives" within the meaning of the FFDCA has no effect on if Behnke's lubricants must be registered as pesticides pursuant to FIFRA.

A. Even the FFDCA and FDA Guidance Clearly State That the FFDCA Does Not Affect FIFRA Jurisdiction

The most compelling language demonstrating that the FFDCA does not in any way curtail or affect FIFRA requirements and jurisdiction can be found in the definition of "pesticide chemical" at Section 201(q)(1) of the FFDCA, where it specifically states:

> *With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.*

Also see Motion to Strike Respondent's Affirmative Defenses and Motion to Compel Discovery (Complainant's Motion to Strike), at 21 -26.

Further, even Respondent's own exhibit supports this assertion:

[1] 40 C.F.R. § 152.5(d) sets forth the "on or in processed food" exemption to FIFRA that Respondent

It is important to note that, depending on the proposed use, an antimicrobial food additive may also be a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As such, it may be subject to registration as a pesticide by the EPA as well as regulation as a food additive.

RX 53 at II, C.

Additionally, the United Stated Food and Drug Administration (FDA) also issued guidance in July of 1999 entitled "Antimicrobial Food Additives - Guidance" (CX 20) which also supports this assertion:

By definition, a substance that is a pesticide chemical under § 201(q) is a "pesticide" within the meaning of FIFRA (§ 201(q)(1)(A) of FFDCA, as amended by ARTCA), and not a "food additive." Such pesticide chemicals are subject to pesticide registration under FIFRA. As discussed earlier, there are exceptions to the definition of a "pesticide chemical" under § 201(q)(1)(B), which exceptions are subject to regulation as food additives under § 409. However, under § 201(q)(1)(B) of FFDCA, as amended by ARTCA, such substances that are excepted from "pesticide chemical" are not excepted from the definition of a "pesticide" under FIFRA. Consequently, such substances that still meet the definition of a pesticide under FIFRA (even though, under FFDCA, they may be regulated as food additives), are subject to registration under FIFRA.

CX 20 at EPA-0541. Also see discussion in Complainant's Motion to Strike, at 27-29.

This is further supported by the sworn Declaration of Mr. Mark Hepp of the FDA, who advised Behnke that it was not unusual for certain substances to be subject to both FIFRA and FFDCA requirements. Mr. Hepp further advised Behnke to contact U.S. EPA regarding any questions relating to FIFRA applicability. See CX 44, ¶¶ 10 and 11.

Further, Behnke remains confused about much of the discussion in the FDA's guidance document, the Food Quality Protection Act (FQPA) and the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA) relating to FDA's and EPA's regulatory authority over antimicrobial substances under the FFDCA. These documents cited by the Respondent only delineate when a product is subject to Section 408 of the

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invokes as a defense.

FFDCA (i.e. when a product falls under U.S. EPA's regulatory authority under FFDCA) and when a product is subject to Section 409 FFDCA (i.e. when a product falls under FDA's regulatory authority under FFDCA). None of these statutory provisions or guidance documents affect U.S. EPA's regulatory authority over antimicrobial pesticides under FIFRA. See Complainant's Motion to Strike, at 22-27.

Clearly, the FDA does not purport to interpret U.S. EPA's FIFRA statute and regulations and leaves it up to U.S. EPA to interpret and implement FIFRA in manner consistent with its remedial purpose.

B. Whether the Lubricants in Question Are "Food Additives" under the FFDCA Is of No Consequence to FIFRA Jurisdiction

Respondent also fails to comprehend the purpose of the definition of "antimicrobial pesticide" under Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm). Complainant's Motion to Strike explains in detail why Section 2(mm) of FIFRA does not limit FIFRA jurisdiction in anyway. See Complainant's Motion to Strike, at 26-29. To belabor the point further is not necessary.

It is noteworthy, however, that Respondent fails to address the extensive legislative history and guidance that U.S. EPA cites to support the assertion that the definition of "antimicrobial pesticide" in Section 2(mm) of FIFRA only affects the timeframe in which FIFRA registration of antimicrobial pesticides must be completed, and in no way limits the definition of a "pesticide" for purposes of FIFRA registration. See Complainant's Motion to Strike, 14-20. To concede that the definition of "pesticide" is not affected by the FFDCA would result in Behnke's inability to argue that the FFDCA has any relevance to the outcome of this case. Doing so would essentially preclude Behnke from arguing Affirmative Defenses 3 through 6.

Further, Behnke has failed to demonstrate to U.S. EPA and this Court how it is subject to Section 409 of the FFDCA[2]. It also refuses to disclose the components of its lubricants to U.S. EPA[3] despite repeated requests. Therefore, it is unclear to anyone but Behnke, if the lubricants in question are exempted out of the definition of "food additive" as it is defined in Section 201(s) of the FFDCA[4]. To date and only a month away from the hearing date, Respondent refuses to disclose this information. Perhaps Behnke is cognizant that the disclosure of this information may cause its arguments regarding Section 2(mm) of FIFRA to vanish.

Nonetheless, the key in determining if Behnke has violated FIFRA is to determine if Behnke's lubricants are "pesticides" under Section 2(u) of FIFRA, and not if they are "food additives" under the FFDCA.

II. Respondent Does Not Become Exempt from FIFRA By Merely Shifting Its Position On the "Intended Use" of Its Lubricants

The "intended use" of the lubricants in question is critical in determining Respondent's liability in this matter. Remarkably, Respondent has shifted its argument regarding the intended use of its lubricants with Micronox antimicrobial technology in an attempt to fit its lubricants under the "on or in processed food" exemption found at 40 CFR §152.5(d). This new explanation of Behnke's intent contradicts Respondent's own pleadings, labeling and advertising claims.

A. Behnke Cannot Escape Its Implicit and Explicit Claims

Since the time that Behnke began to advertise the benefits of it Micronox

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[2] Section 409 of the FFDCA regulates "food additives."

[3] U.S. EPA routinely protects such proprietary information from the public.

[4] It is strange therefore that Behnke is asking this Court to make a determination as to whether its lubricants are "food additives" (Response to MAD, at 25), given the fact that it has failed to provide this Court with adequate information to make such a determination. Nonetheless, this Court does not have jurisdiction over such FDA matters in this proceeding. Additionally, such a determination is unnecessary

antimicrobial technology (in approximately 2001) it made implicit and explicit claims that fall into three distinct categories:

(1) Behnke made antimicrobial claims that the lubricants protect themselves from harmful microorganisms (See CX 1, at Bates numbers EPA-0021, EPA-0023, EPA-0025; CX 6a, at EPA-0104; CX 6c, at EPA-0152, EPA-0153, EPA-0154, EPA-0156, CX 8, at EPA-0186, EPA-0188; CX 8a, at EPA-0208, EPA-0210, EPA-0212, CX 12, at EPA-0303, EPA-0305, EPA-0308, EPA-0312; CX 36, at EPA-0751; CX 46, at EPA-0890 and EPA-0891.)

(2) Behnke made antimicrobial claims that implied that the lubricants protect the equipment from harmful microorganisms. (See CX 1a, at EPA-0057; CX 6a, at EPA-0104 and EPA-0116.)

(3) Behnke made antimicrobial claims that the lubricants control harmful microorganisms with out any qualification as to where the lubricants control the microorganisms (See CX 1, at Bates number EPA-0021 and EPA-0025; CX 1a, at EPA-0057 and EPA-0058; CX 3, at EPA-0061, EPA-0062, EPA-00 66 and EPA-0071; CX 4, at EPA-0072, EPA-0074, EPA-0077 and EPA-0078; CX 5, at EPA-0082; CX 6a, at EPA-0102, EPA-0106, EPA-0110, EPA-0112, EPA-0113 and EPA-0118; CX 6b, at EPA-0123, CX 6c, at EPA-0141, EPA-0155 and EPA-0164; CX 6d, at EPA-0173; CX 8, at EPA-0184, EPA-0186, EPA-0187 and EPA-0188; CX 8a, at EPA-0208, EPA-0209; CX 8b, at EPA-0242, EPA-0243, EPA-0249; CX 8ca, at EPA-0253, EPA-0256, EPA-0257, EPA-0259, EPA-0270, EPA-0271; CX 9, at EPA-0279, EPA-0283, EPA-0285; CX 10, at EPA-0291; CX 11, at EPA-0297, EPA-0298; CX 12, at EPA-0305, EPA-0310, EPA-0312; CX 13, at EPA-0324; CX 15, at EPA-0353; CX 35, at EPA-0726, EPA-0727,

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to determine if Behnke has violated FIFRA.

EPA-0730, EPA-0732, EPA-0733, EPA-0735; CX 46, at EPA-0880, EPA-0882 and EPA-0890.)

In its complaint filed against NSF, Behnke reiterated that its Micronox antimicrobial technology is intended to protect the lubricant itself. See CX 36 at ¶ 5.

In its Answer to U.S. EPA's Complaint in this matter, Behnke reiterated this intent in Affirmative Defense 6:

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.

Realizing that these claims result in the need to register its lubricants under FIFRA, Behnke now shifts its explanation as to what the Micronox antimicrobial technology is intended to accomplish. After claiming for more than six years that the purpose of the antimicrobial technology was to protect the lubricant or equipment from harmful microorganisms, Behnke now claims that its lubricants may be reasonably expected to result in becoming a component of food and in doing so the Micronox antimicrobial technology *"will mitigate or control the microbial population found on or in the food that it contacts."* Response to MAD, at 28[5].

This is a blatant attempt to tweak its words to conform to FIFRA's exemption under 40 CFR § 152.5(d). Behnke's implication that the lubricants are only intended to control microorganisms at the moment the lubricants make contact with the processed food and not a moment before, is disingenuous, self serving and contradicts the undisputed evidence. Certainly, this latest explanation of the intended purpose of the

[5] It is important to note that such a shift may well affect Behnke's claimed status with FDA. 21 C.F.R. § 170.3(o)(2) lists antimicrobial agents as a direct human food ingredient that may be added to food. Behnke's own exhibit 53 specifies data requirements that are necessary for antimicrobial food additives which include a showing of efficacy. Behnke's departure from its initial labeling and advertising claims

Micronox antimicrobial technology is a significant shift from what Behnke has been claiming historically, and is inconsistent with the claims Behnke made at all times relevant to the alleged violations. Additionally, Behnke's eleventh-hour repositioning does not change the actual intent that Behnke had (and continues to have) when adding the Micronox antimicrobial technology into its lubricants.

Behnke even concedes that *"with the benefit of 20:20 hindsight, perhaps Behnke could have avoided this entire litigation,"* Response to MAD, at 27. Behnke is correct that this litigation could have been avoided. However, Behnke is incorrect about the manner in which it could have avoided litigation. U.S. EPA has informed Behnke that it could avoid this litigation in three ways:

(1) By registering its lubricants with U.S. EPA under FIFRA;

(2) By registering its additive, Micronox, with U.S. EPA under FIFRA. Much like Petro-Canada (See CX 18e and 18f), it could then have enjoyed the "treated articles exemption" under FIFRA (40 CFR 152.25(a)) as long as it complied with PR Notice 2000-1; or

(3) By removing all antimicrobial claims from its labeling and advertising of these lubricants.

Rather than exercising any of these options, Behnke opts to twist its claims in an attempt to circumvent FIFRA. Yet, this can not be done because the implied claims remain the same. Given the fact that the Micronox antimicrobial technology is an inherent part of the lubricants, it follows that the lubricants will begin to control harmful microorganisms the instant the microorganisms make contact with the lubricants. The

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could then open up a whole host of FDA requirements. In any case, Behnke is mistaken that it does not need to demonstrate efficacy.

Micronox antimicrobial technology is at work well before it makes contact with any food.

Even Behnke's own explanation of its customer Kraft's requests reveals the actual intended purpose of the Micronox antimicrobial technology. *"Behnke's customer was also concerned that microbes contained in the cream cheese water mix would multiply within Behnke's lubricant and, then, as the lubricant further contacted the cream cheese, it would, contaminate the finished product with undesirable levels of microbes. The customer asked whether Behnke could formulate an H1 lubricant that could reduce the risks of such cross-contamination, thus eliminating the lubricant as a "hot spot" for microbial contamination under Kraft's HACCP evaluation process."* Response to MAD, at 8 and ¶ 16 of Peter Declaration. In response to Kraft's request *"Behnke was able to improve upon the resistance of its lubricants to food borne microbes and, thereby reduce the risk of cross-contamination of processed foods of which the lubricants would become a part."* Response to Mad, at 9 and ¶ 19 of Peter Declaration. After reformulation and testing, Behnke explains that *"this was a major breakthrough as the product achieved the customer's lubricant needs while also improving food safety by eliminating a host [the lubricant] for the growth of undesirable levels of food borne microbes."* Response to MAD, at 9 and ¶ 20 of Peter Declaration. Clearly, the intent of the Micronox antimicrobial technology was and is to control microorganisms in the lubricant to prevent any cross-contamination to the food.

Further, Mr. Bill Bayliss' declaration corroborates this intent:

As potential food contact materials, microbes in or on foods that we want to contain and not spread throughout out plant could be transferred to the JAX products as used for their intended purpose. That JAX products resist contamination from such food borne microbes is beneficial to our HACCP efforts in that it could limit the risk of cross-contamination.

Response to MAD, at 7 and ¶ 4 of Bayliss Declaration. Clearly, Behnke is claiming, even to date, that the lubricant with Micronox antimicrobial technology is working to control harmful microorganisms in the lubricant itself to prevent cross-contamination.

Further 40 C.F.R. § 152.15 discusses intent:

A pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

(a) The person who distributes or sells the 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; or (2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or

(b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or

(c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

It is evident that Behnke's attempt to redefine its "intent" will not allow it to escape either 40 C.F.R. § 152.15(a) nor (c).

B. Behnke's Lubricants Are Not "Processed Foods"

Behnke also suggests that its lubricants are themselves "processed food." Respondse to MAD, at 22-23. Behnke attempts to equate the definition of "on or in processed food" at 40 C.F.R. § 152.5(d) with the definition of "food" in the FDA regulations. Yet, it fails to offer any support for doing so. On the contrary, the U.S. EPA does not consider food contact items (such as Behnke's lubricants) to be "processed foods" within the meaning of FIFRA. See Complainant's Motion for Accelerated Decision on Liability and on Affirmative Defenses and Memorandum in Support of the Motion (MAD), at 50-52 and CX 19 at EPA-0523.

To suggest that the lubricants are "edible food" is misguided and a stretch that defies the plain meaning of "food." Respondent cites to the definition of "food" at 21 CFR § 170.3(m). Even under this definition, which does not interpret FIFRA's definition of "processed food," the lubricants still do not fit the definition until such time as a trace or insignificant amount of lubricants becomes a component of food through incidental and indirect contact.

Behnke is focused on whether the lubricants are "edible food" or "food" when it should actually focus on whether the lubricants are "processed foods" as that term is used in the FIFRA regulations at 40 CFR 152.5(d). As a result of its misplaced focus, Behnke chooses to omit any citation to the definition of "processed food" in Section 201(gg) of the FFDCA. It also fails to respond to U.S. EPA's well supported discussion of what constitutes a "processed food" in its MAD. Therefore, Behnke cannot legitimately argue that its lubricants are "processed food" for the purpose of 40 CFR § 152.5(d).

C. Behnke's Lubricants are Not Intended to Treat "Processed Foods"

Respondents refuses to accept the fact that the "on or in processed food" exemption is intended for situations when an antimicrobial products is actually applied "on or in" processed food for the purpose of controlling harmful microorganisms. The plain language could not be clearer. The lubricants in question are not being applied "on or in processed food[6]." The lubricants are not intended to treat "processed foods."

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[6] Interestingly, Behnke never discusses the fact that its lubricants are indirect food additives. It does concede that its lubricants are subject to 21 C.F.R. § 178.3570. See Affirmative Defense 5 in its Answer. 21 C.F.R. Part 178 is entitled "Indirect Food Additive: Adjuvants, Production Aids and Sanitizers." *"In general, these [indirect food additives] are food additives that come into contact with food as part of packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on food."* (Emphasis added) (See CX 68 at the definition of "Indirect Food Additive." Therefore, Respondent's own arguments regarding whether the lubricants are "processed food" under 152.5(d) begin to fall apart and are internally inconsistent. On the one hand, Behnke claims that the lubricants comply with 21 C.F.R. § 178.3570 as "indirect food additives." On the other hand, Behnke

They are not preservatives. The lubricants lubricate equipment involved in the processing of food. The lubricants lubricate equipment involved in the processing of food.

As Behnke points out itself, *"Micronox is not, however a substance that exists separate from the lubricant that incorporate the technology. There is not a "formula" for Micronox and one cannot purchase Micronox as an additive for any other products."* Response to MAD, at 9 and ¶ 20 of Peter Declaration. Logically, the antimicrobial technology is at work in the lubricant well before it ever makes any contact (if at all) with any processed food. In accordance with the FFDCA requirements, only trace amounts or negligible levels of the lubricants are permitted to make contact with processed food. See 21 C.F.R. § 174.6, 21 C.F.R. §178.3570 ("Limitations"), CX 66 at "What is a Food Additive?" and CX 68 at "Indirect Food Additive."

It is clear that the lubricants are intended to lubricate equipment, and not to treat processed food. The lubricants are therefore not considered by U.S. EPA to be "processed foods."

Looking at the totality of the claims and arguments Behnke has made in the past, coupled with the types of testing Behnke alludes to in its advertising, it is clear that Behnke can not avoid FIFRA requirements by trying to fit its lubricants in to the "on or in processed food" exemption under 40 CFR § 152.5(d).

III. Behnke Cannot Create Exemptions Where None Exist

Behnke makes much about the fact that its customer base is comprised of

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claims that "*the antimicrobial properties of the Lubricants are intended to control or mitigate microorganisms 'in or on processed foods' only.*" Response to MAD, at 27-28. Behnke therefore implies that the lubricants are intended to be added to food, become a component of food or have a technical effect in or on food. However, Behnke's own assertion that its lubricants are "indirect food additives," contradicts

"sophisticated buyers" exclusively in the food and beverage processing markets. Nowhere in the FIFRA statute or its implementing regulations is there an exemption for pesticide registration for instances when a product is being sold exclusively to a particular industry.

A. FIFRA Requires Registration of Pesticides No Matter to Whom the Pesticides Are Being Sold

Behnke suggests that it does not need to register is lubricants because it only sells its lubricants to food and beverage processing industries. It states *"unlike the typical customer 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."* Response to MAD, at 26. While this may or may not be true, it does not in any way absolve Behnke from having to register its lubricants.

Behnke essentially argues that it is unnecessary to inform its "sophisticated buyer" of the intended effects of its lubricants with Micronox antimicrobial technology because the "sophisticated buyer" already knows that the intended purpose is to control microbes "on or in processed foods." This begs the question as to why Behnke undertook such a massive advertising campaign to explain the effects of its Micronox antimicrobial technology to its customers over the past six to seven years. Further, Behnke contradicts itself when it states: *"Behnke undertook advertising and promotion of its food grade lubricants featuring the Micronox® technology in food and beverage processing plant machinery. Behnke believed 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."* Response to MAD, at 9-10.

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its assertion that its lubricants are being applied on processed food in order for the Mirconox technology to

Behnke further argues that the *"appropriate issue is what a reasonable consumer of its Lubricants in its limited market would understand about the intended use of the Lubricants from the information provided by Behnke."* Response to MAD, at 30. Having no statutory or regulatory authority to cite to, Behnke cites to case law to support its assertion. However, it fails to look at the holdings of these cases in their totality.

Indeed the holding in *N. Jonas & Co., Inc. v. United States Environmental Protection Agency*, 666 F. 2d 829 (3rd Cir. 1981) is relevant in its discussion of determining intent objectively. In *Jonas*, the question was whether a product that had no pesticidal labeling claims associated with it was in fact a pesticide. The Court rejected Respondent's argument that it must look at Respondent's subjective intent to determine if the product was a pesticide. The Court accepted U.S. EPA's argument that the *"product is a pesticide if a reasonable consumer - given the label, accompanying circulars, advertising representations and the collectivity of the circumstances - would use it as a pesticide. The fact that the product may also have other uses does not affect the need to register,"* 666 F. 2d at 832. In this context, the court held that in *"determining intent objectively, the inquiry cannot be restricted to a product's label [which was absent of pesticidal claims] and to the producer's representations. Industry claims and general public knowledge can make a product pesticidal not withstanding the lack of express pesticidal claims by the producer itself. Labeling, industry representations, advertising materials, effectiveness and the collectivity of all the circumstances are therefore relevant."* 666 F. 2d at 833. See also, *In the Matter of: FRM Chem, Inc. A.K.A. Industrial Specialties*, Docket No. FIFRA-07-2004-0041, 2005 WL 528482 (E.P.A.) (February 16, 2005), *In the Matter of Hing Mau, Inc.*, Docket No. FIFRA-9-2001-0017,

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control microorganisms "in or on processed food."

2002 WL 2005523 (E.P.A.) (August 13, 2002), *In Re Matter of Rug Doctor, Inc.*, FIFRA-09-0375-C-84-8, 1985 WL 57117 (E.P.A.) (June 6, 1985), *In Re: The Bullen Companies, Inc.* 2001 WL 185489 (E.P.A.), 9 E.A.D. 620 (February 1, 2001) (*"when a person who distributes or sells a product explicitly or implicitly claims that the product is a pesticide, FIFRA requires that product to be registered as a pesticide"*), and *In The Matter of Chemo. Industries, Inc.*, 1984 WL 50057 (E.P.A.) (January 24, 1984).

In *In re Contact Industries, Inc.*, 1978 EPA ALJ LEXIS 11, *8 (September 25, 1978), in discussing intent, the court provides this insight:

> *In interpreting broad remedial legislation, the consumer is not assumed to be an expert or one possessing special knowledge or ability, and includes "the ignorant, the unthinking, and the credulous."*

Unlike in Jonas, the fact patterns in this matter regarding claims and intent are clear. Given the extensive implicit and explicit claims made by Behnke both in its labeling and advertising, there is no need to impute intent from the "reasonable customer." See also 40 CFR § 152.15, which discusses "intent." Further, as stated in Mr. Josh Rybicki's sworn Declaration (CX 16), it is evident that at least some of Respondent's "sophisticated buyers" understood Behnke's implicit and explicit claims to mean that the lubricants in and of themselves contained antimicrobial properties and as a result reduced the colony counts of bacteria in the lubricants. See also ¶ 4 of Bayliss Declaration.

B. FIFRA Jurisdiction Is Not Dictated By How Registration May Effect Behnke's Sale of Its Lubricants

Interestingly, Behnke argues that *"EPA registration of its products 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 Section 409 of the FFDCA." Response to MAD, at 26.

No where in FIFRA does the statute require the U.S. EPA to consider how registration might impact an individual company's sale of the pesticidal product. Behnke's suggestion is incongruous.

It is also curious that Behnke credits its customers with enough knowledge to understand the intended purpose of Micronox but not with enough knowledge to understand that the registration of the lubricants in no way alters the components of the lubricants. Behnke has repeatedly advertised that the lubricants controls deleterious microorganisms such as Escherichia coli, (E. coli), Lysteria monocytogenes, (Lysteria), and Salmonella typhimurium, (Salmonella). To now suggest that registration of the lubricants will create a "chilling effect" is both irrelevant and unsubstantiated. On the contrary, there is already an antimicrobial lubricant on the market that has complied with FDA and U.S. EPA requirements (See Petro- Canada's Microl antimicrobial additive for lubricants at CX 18 e and f). To allow Behnke to escape the FIFRA requirements would afford Behnke an unfair competitive edge over its competitors.

IV. Objections and Clarifications

Behnke refers to numerous additional witnesses and documentation that it had not submitted in its Prehearing Exchange. U.S. EPA objects to the manner in which Behnke now attempts to add these witnesses and documentation into the record.

Behnke misquotes U.S. EPA in its Response to MAD at page 22. Behnke states that "Factually, the EPA itself concedes that *"[i]n food processing facilities such microorganisms [Salmonella and E. Coli] can only originate from the processed meat." (Id. at 52-53).*" The statement made by U.S. EPA in its entirety was "*In food processing*

facilities, such microorganisms can only originate from the processed meat (or the humans working in the processing facilities)."

V. Conclusion

The only questions that remain are questions of law, not fact. It is clear however, that Behnke wishes to have a hearing on this matter despite the fact the absence of genuine issues of material fact. It wishes to argue interpretations of law before this Court, including laws that are irrelevant to this proceeding. Respectfully, U.S. EPA remains prepared to proceed to hearing should this Court decide that such a hearing is appropriate. However, U.S. EPA stands on it assertion that based on the current pleadings, admissions and declarations on file, there are no genuine issues of any material fact as to Respondent's liability for the alleged violations and the questions of law are ripe for accelerated decision. The Complainant is therefore, entitled to judgment as a matter of law as to liability for all eleven counts alleged in the Complaint and respectfully requests that Complainant's MAD be granted.

Respectfully Submitted,

2/27/08

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

Date

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

CERTIFICATE OF SERVICE

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

Dated in Chicago, Illinois, this 27 day of February 2008.

Patricia Jeffries-Harwell
Legal Technician
U.S. EPA, Region 5