definition of "food." 21 C.F.R. § 170.3(m) states that "[f]ood includes human food [and] substances migrating to food from food-contact articles." Based on this definition, Respondent asserts that "the Lubricants are indeed edible food articles and *are not*, therefore, subject to the same FIFRA registration as floor cleaners or wall sanitizers." R's Post-Hearing Brief, p. 11. In support of this argument, Respondent claims that testimony from witnesses provides evidence that Behnke's lubricants become part of processed foods. R's Post-Hearing Brief, p. 11.

While it is true that Behnke's lubricants may come in contact with processed food, in his testimony, Mr. Peter, the President of Behnke, stated that the lubricants are not designed to be applied onto or added into the processed food under the FDA. Tr. April 2, p. 718. This was further illustrated by the testimony of Mr. Rybicki, Inventory Control for American Foods Group, who testified that at the meat packing plant where he works, if the lubricant gets on the meat, "the meat is retained, shown to a USDA inspector. They will cut, like, the area or part of that the oil is on and then they will inspect it again. And then the USDA will either say yes or no if we can put it back onto production or if we have to condemn the carcass or piece of meat." Tr. March 31, p. 119. Carter Anderson, Respondent's witness and a Behnke salesman, testified, "[m]any types of lubricant come in contact with the food product. Everybody does everything they can to prevent that from happening." Tr. April 3, p. 874. It is clear from this testimony that the lubricants and greases used on the food processing plant machinery are not "food." I find that the Respondent's argument is without merit and that Behnke's lubricants are not "food" exempt from FIFRA regulation.

Behnke's lubricants protect only themselves from environmental contaminants

In its sixth defense, Respondent asserts that the intended use of Behnke's antimicrobial lubricants is simply "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." Answer p. 28. Respondent appears to be arguing that its lubricants are "treated articles or substances" as described in 40 C.F.R. § 152.25(a) and, therefore, are not required to be registered under FIFRA.

To qualify for the "treated articles or substances" exemption, the substance must meet the regulatory definition: "[a]n article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use." 40 C.F.R. § 152.25(a). As Complainant points out, this exemption only applies if Behnke's lubricants were treated with a pesticide that has been registered under FIFRA for use in protecting the lubricant. Respondent has failed to produce any evidence that the lubricants at issue contain or were treated with a pesticide registered with the EPA under FIFRA for use as an antimicrobial. C's Motion to Strike, pp. 29-30.

I find that Respondent's argument that its products fall within the "treated articles or substances" exemption has no merit.

Behnke's lubricants are not exempt from FIFRA under the "on or in processed food" exemption

Respondent's main argument is that its lubricants are not pesticides because they are not intended for preventing, destroying, repelling, or mitigating any "pest" within the meaning of FIFRA, because Behnke's lubricants target microbes "on or in processed foods" which are not "pests" within the meaning of FIFRA. Answer p. 28, R's Reply Brief, pp. 1-5. Mr. Peter testified that Behnke developed the antimicrobial lubricants in response to a problem faced by a large food company in its food processing facilities. Apparently, the company was concerned that the ball bearings in its equipment were transferring microbes to its processed food. Tr. April 2, pp. 585-592. Respondent argues 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." R's Reply Brief, p. 2.

Mr. Peter and Mr. Paquette, the technical director at Behnke, both testified that the lubricants are not intended to be applied directly to the food. Tr. April 2, p. 718; Tr. April 3, p. 806. Larry Cooper, Industrial Maintenance Mechanic at Quaker Oats, testified that they discarded food that had grease on it. Tr. April 3, p. 852. Certainly, none of the lubricants' labeling instructed users to apply the lubricant directly to food. Respondent argues that "although Behnke's Lubricants may not be specifically designed to become 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." R's Reply Brief, pp. 4-5.

Complainant argues that the plain language of 40 C.F.R. § 152.5(d) clearly states that the "on or in processed food" exemption only applies to products that are directly added to or placed onto the food to kill or mitigate microorganisms. C's Post-Hearing Brief p. 58.[6] Complainant states "for an antimicrobial product to be exempt from FIFRA regulation by virtue of its targeting only microogranisms that are 'on or in processed food,' the antimicrobial product has to be intended for application directly onto 'food that has undergone processing and is intended to be consumed immediately or after some further processing or preparation' - i.e., 'edible food articles.'" C's Post-Hearing Brief, p. 59. Therefore, antimicrobial substances used in food contact items such as paper or paperboard are considered to be "pesticides" under FIFRA by the

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[6]The EPA cites to the *"Legal and Policy Interpretation of the Jurisdiction under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances,"* 63 Fed. Reg. 54533 (October 9, 1998), which was jointly issued by the FDA and the EPA for the definition of "processed food" used when applying this exclusion. EPA interprets "processed food" "as they are commonly understood–food that has undergone processing and is intended to be consumed immediately or after some further processing or preparation." C's Ex. 19.

EPA. C's Ex. 19. Complainant points out that the evidence produced at the hearing demonstrates that none of Behnke's lubricants are intended to be applied directly to food. The EPA argues that if the lubricants are not intended to be applied directly to processed food, the lubricants are not exempt from FIFRA under the "on or in processed food" exemption. C's Post-Hearing Brief, p. 59; C's Ex. 19.

Based on his 32 years experience at the EPA, Mr. Edwards testified that, in his opinion, the exemption does not apply to Behnke's lubricants. He came to this opinion after reviewing Behnke's literature and noting that none of the directions require the lubricant to be applied directly to, in, or on processed food. Mr. Edwards noted that the lubricants are intended to lubricate machinery, and only become part of the processed food through incidental contact. Tr. April 1, p. 329.

To help clarify our understanding of the "on or in processed food" exemption in 40 C.F.R. § 152.5(d), Mr. Edwards gave an example of a product where the "on or in processed food" exemption does apply. He named a Proctor & Gamble product called Fit which was applied to lettuce, tomato, and other items in restaurants' salad bars. According to Mr. Edwards, this antimicrobial product was used to prevent spoilage and bacteria. He noted that it was applied directly to the food and not to the counter or any other surface. Tr. April 1, pp. 322-324. From this example, it is clear that Behnke's lubricants do not fall within the "on or in processed food" exemption as they are not applied directly to processed food.

As the Complainant persuasively points out, this matter is analogous to that faced by the federal court in *Kenepp v. American Edwards Laboratories*, 859 F. Supp. 809 (E.D. PA 1994). C's Post-Hearing Brief, pp. 56-57. The court in *Kenepp* was faced with the question of whether an antimicrobial product that targeted the Human Immunodeficiency Virus Type 1 ("HIV") on hospital instruments was a pesticide under FIFRA. The court found that the antimicrobial products were indeed pesticides within the meaning of FIFRA. Although the targeted microorganisms originates from a human being, it does not mean that the microorganism is always considered "on or in living man." Thus, when HIV contaminates a hospital instrument the microogranism is no longer "on or in a living man" and a product intended to kill the microorganism on the instrument is a pesticide requiring FIFRA registration. *Kenepp v. American Edwards Laboratories*, 859 F. Supp. 809, 816, n. 4(E.D. PA 1994).

Similarly, if a microorganism such as E.coli originates from processed food, and contaminates the machinery or the lubricant on that machinery, it is no longer "on or in processed food" and an antimicrobial product (such as Behnke's lubricants) that targets that microorganism on the machinery and/or in the lubricant is considered a pesticide under FIFRA. C's Post-Hearing Brief, pp. 56-57. Clearly, the antimicrobial lubricants were intended to protect the lubricants themselves and the equipment they touched, therefore preventing cross-contamination within the food processing facility.

Respondent's "on or in processed food" argument fails on another ground as well.

Complainant has produced evidence that the microbes meant to be mitigated by Behnke's lubricants, E.coli, Listeria, and Salmonella, do not necessarily originate in processed food nor may they be found solely on processed food. Dr. Blackburn testified that E.coli, Listeria and Salmonella can enter food processing facilities on the workers themselves. Additionally, in a food processing facility such as a cattle slaughter house, the animals track in fecal matter, or are covered in fecal matter, which has bacteria in it. The equipment in these facilities may become contaminated through the aerosolization of the microbes via blood splatter or fecal splatter. Within other food processing facilities, vegetables can become contaminated with microbes through manure used to fertilize the plants, from untreated water, and from the workers who handle the vegetables. Tr. April 1, pp. 476-480. Thus, the record shows that microbes can enter food processing facilities in a variety of ways, and then cross contaminate. There are microbes that do not originate "on or in processed food" and can be found elsewhere in the food processing facility. Therefore, Behnke's lubricants are not exempt under 40 C.F.R. § 152.5(d).

I find Complainant's argument persuasive for the reasons stated above and that Respondent's argument is without merit. Behnke's lubricants do not fall under the "on or in processed foods" exemption. The evidence itself clearly reflects that the intended use of the lubricants was not limited to mitigating bacteria on or in processed food. It is clear that the antimicrobial properties of the lubricants are intended to function on the lubricant itself, and on the equipment in the food processing facilities. Further, I find that the language used in the labels and advertising by Behnke clearly makes pesticidal claims not exclusively limited to a "on or in processed food" exception.

Behnke's lubricants are not exempt under a "reasonable consumer within the context of the market" argument

Respondent also argued at the hearing and in its Post-Hearing Brief that Behnke only markets and sells its lubricants for use by the food and beverage processing industry. Respondent claims Behnke's customers are aware that lubricants used in their plants will inevitably come into contact with their food and that Behnke's customers are sophisticated enough to know that Behnke's antimicrobial claims apply only to controlling microbes in or on processed foods. Therefore, Respondent claims, the lubricants are not pesticides. R's Post-Hearing Brief pp. 10-14.

In support of this argument, Respondent cites to *In the Matter of Caltech Indus., Inc.*, Docket No. 5-FIFRA-97-006 (ALJ June 9, 1998), which involved the sale and distribution of an unregistered pesticide in violation of FIFRA. Respondent argues that the ALJ concluded that the "intended use" of the product (in this case, Hospital Cleaning Towels with Bleach) must be considered applying the "reasonable consumer" objective standard and that the "reasonable consumer" must be understood within the context of the market for the product, such as the health care industry in *Caltech*. Respondent claims that a reasonable consumer in the food and beverage processing industry is concerned with microbes contaminating processed food, of which the lubricants may become a part. R's Post-Hearing Brief pp. 15-16.

I find Respondent's reliance on *Caltech* as support for its "reasonable consumer" argument misguided. While the Respondent in *Caltech* made a similar "reasonable consumer within the context of the market" argument, the ALJ denied the Complainant's motion for accelerated decision without addressing the merits of the parties' arguments. The ALJ noted in his order that the arguments of the parties could only be properly evaluated after an evidentiary hearing. *Caltech* eventually settled without an evidentiary hearing and without a final ruling on the respondent's "reasonable consumer" argument. Therefore, *Caltech* is not controlling in this matter. *In the Matter of Caltech Indus., Inc.*, Docket No. 5-FIFRA-97-006 (ALJ June 9, 1998). Finally, while I respect my colleagues' opinions, I am not bound by their decisions.

The EPA argues that Respondent's contention that Behnke's lubricants are sold to sophisticated food and beverage processing costumers is irrelevant to a determination of whether Behnke's lubricants are "pesticides" under FIFRA. Complainant contends that there is no exemption for registration of pesticides under FIFRA based on the customer to which the pesticide is sold. C' Reply Brief, p. 2. Even assuming that there was an exemption for products sold to a certain market, Complainant argues that there is nothing that limits the sale and use of Benhke's lubricants to the food processing industry. The EPA points to testimony from Mr. Peter, in which he stated that the lubricants could be sold to costumers outside of the food and beverage processing industry. C's Post-Hearing Brief, pp. 85-87. Under questioning by EPA counsel, Mr. Peter admitted that he would sell the lubricants to whoever wanted to buy them. Tr. April 2, p. 645.

I find that even if Behnke's lubricants are sold exclusively to the food and beverage processing industry, FIFRA and its implementing regulations do not include a pesticide registration exemption for instances when a product is being sold exclusively to a particular industry. FIFRA requires registration of pesticides regardless of the identity of the buyers. Having sophisticated customers does not absolve Respondent from meeting the regulatory and statutory requirements.

IV. PENALTY

Penalty Criteria

The Consolidated Rules of Practice govern the assessment of civil administrative penalties in this proceeding. Section 22.27(b) of the Consolidated Rules of Practice provides in pertinent part:

> [i]f the Presiding Officer determines that a violation has occurred and the complaint seeks a civil penalty, the Presiding Officer shall determine the amount of the recommended civil penalty based upon the evidence in the record and in accordance with any civil penalty criteria in the Act. The Presiding Officer shall consider any civil penalty guidelines issued under the Act...If the Presiding Officer decides to assess a penalty different in amount from the penalty proposed by complainant, the Presiding Officer shall set forth in the

initial decision the specific reasons for the increase or decrease.

40 C.F.R. § 22.27(b). The Complainant bears the burdens of presentation and persuasion to show that the relief sought in this case is "appropriate." 40 C.F.R. § 22.24(a).

In regard to any relevant "civil penalty criteria in the Act," Section 14(a) of FIFRA, 7 U.S.C. § 136l, governs the assessment of civil penalties for violations of Sections 3(a) and 12(a) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j (distribution or sale of unregistered pesticides). Section 14(a)(1) of FIFRA authorizes the assessment of civil administrative penalties of up to $ 5,000 per offense. 7 U.S.C. § 1361(a)(1). The Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, and its implementing regulations at 40 C.F.R. part 19, increased the statutory maximum penalty to $6,500 for each violation of FIFRA that occurs on or after March 15, 2004.[7] 31 U.S.C. § 3701; 40 C.F.R. § 19.4.

Section 14(a)(4) of FIFRA further provides in pertinent part that:

> In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to:
>
> [1] the size of the business of the person charged,
>
> [2] the effect on the person's ability to continue in business, and
>
> [3] the gravity of the violation.

7 U.S.C. § 136*l*(a)(4) (numeration added).

To assist enforcement officials in taking the above factors into consideration when assessing penalties under FIFRA specific to any given case, on July 2, 1990, the EPA's Office of Compliance Monitoring, Office of Pesticides and Toxic Substances issued an Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act ("the ERP"). C's Ex. 33. The ERP sets forth a "five stage process" for computing a penalty in consideration of the three statutory penalty criteria set forth in Section 14(a)(4) of FIFRA. C's Ex. 33 at 18. The ERP is a guidance document intended to provide a rational, consistent and equitable calculation methodology for applying the statutory factors to particular cases. Compl. p. 39. While the

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[7]Pursuant to section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, each federal agency is required to issue regulations adjusting for inflation the maximum civil monetary penalties that can be imposed pursuant to such agency's statutes. The purpose of these adjustments is to maintain the deterrent effect of federal civil penalties and to further the policy goals of the laws. U.S. EPA publishes inflation-adjusted maximum penalties pursuant to the Debt Collection Improvement Act under 40 C.F.R. part 19.

ERP is not binding on Administrative Law Judges, the EAB has emphasized that the Agency's penalty policies should be applied whenever possible. *In re Carroll Oil Co.*, RCRA (9006) Appeal No. 01-02, 10 E.A.D. 635, 656 (EAB, July 31, 2002). However, a penalty policy is not unquestioningly applied as if the policy were a rule with "binding effect." *Employers Insurance of Wausau and Group Eight Technology, Inc.*, TSCA Appeal No. 95-6, 6 E.A.D. 735, 755-762 (EAB, Feb. 11, 1997). The ALJ is required to consider the civil penalty guidelines but may give specific reasons for deviating from the amount of the penalty proposed by the Complainant. 40 C.F.R. § 22.27(b).

Discussion of Penalty Criteria

In the Complaint filed against Respondent and at the hearing, the EPA proposed a total civil penalty of $ 50,050 for the violations of FIFRA cited in Counts 1 through 11. Complainant argues that it properly applied the FIFRA statutory penalty factors and the ERP, it has met its burdens, and the imposition of a penalty of $50,050 is appropriate in this case. Mr. Robert Bonace, a Life Scientist with the EPA, testified that he calculated this penalty for the EPA utilizing the ERP. Tr. March 31, p. 186. Complainant also hired an outside consultant on financial analysis, Mr. Mark Ewen of Industrial Economics, to help calculate the proposed penalty. C's Post-Hearing Brief, p. 109. *See also* C's Ex. 32.

Respondent argues that the penalty proposed by the EPA is excessive and that the appropriate penalty is $0, or at most, $2,275 per violation. Resp's Post-Hearing Brief p. 17.

Size of the Business

The EPA first considered the appropriateness of the proposed penalty by examining publicly-available financial information on Behnke. Relying upon a Dun & Bradstreet report (C's Ex. 14b), which reflected that Respondent had annual gross sales in the amount of $7,900,000, Mr. Bonace determined that the penalty was appropriate for a business this size. Tr. March 31, p. 189; C's Post-Hearing Brief, p. 109. Respondent has explicitly waived any challenge to the proposed penalty based on the size of business. R's Post-Hearing Brief pp. 16-17.

The Effect on the Person's Ability to Continue in Business

The EPA stated that it considered the effect of the proposed penalty on Respondent's ability to continue in business. In doing so, Complainant hired an outside consultant in financial analysis, Mr. Mark Ewen of Industrial Economics. Mr. Ewen was hired to review several different items of publicly-available information regarding Behnke's financial condition. C's Post-Hearing Brief, p. 109; C's Ex. 32.

However, Respondent admitted in its prehearing exchange that it would be able to pay the total penalty proposed in the Complaint and specifically waived any objection to the proposed

penalty based on its inability to pay or the effect on Behnke's ability to continue in business. R's Resp. To Mots. To Strike and Compel at 24. Moreover, in Respondent's Post-Hearing Brief, Respondent again waived any challenge to the proposed penalty based on inability to pay. R's Post-Hearing Brief, pp. 16-17. *See also* Tr. March 31, p. 190. Respondent has also declined to provide any evidence concerning its financial condition, which would be necessary in order to support an inability to pay claim. *In re New Waterbury*, 5 E.A.D. 529, 541-542 (EAB 1994).

Gravity of the Violation

Complainant contends that the proposed penalty of $50,050 is appropriate in light of the "gravity" of the violations. Complainant argues that Respondent's violations of FIFRA present a potential danger to public health, and therefore involve substantial gravity. Complainant notes that Respondent's violations involve the distribution or sale of unregistered pesticides. Respondent claimed that these pesticides would be effective against harmful bacteria such as Listeria, E. coli, and Salmonella but failed to submit their products to the EPA's efficacy evaluation process. Complainant argues that Behnke introduced into commerce products that made antimicrobial claims, but that had never been proved to be effective under the strict EPA efficacy evaluations in controlling microorganisms to the extent that Behnke claimed in its labeling and advertisements. C's Post-Hearing Brief, pp. 110-111.

Potential Harm to the Public

Dr. Blackburn testified about the importance of EPA's efficacy evaluations in order to ensure that antimicrobial products are as effective as advertised. As discussed above, Behnke's lubricants at issue were labeled as targeting bacteria such as Listeria, E.coli, and Salmonella. Dr. Blackburn testified that advertising claims that mention such bacteria are "public health claims" and therefore very important to the EPA. Tr. April 1, p. 485. Dr. Blackburn stated that efficacy evaluations of antimicrobials are:

> critical because these organisms are public health organisms. We know that they directly impact man, are infectious to man, they're pathogenic towards man. And it's important that we have the confidence that these products will work against these pathogenic organisms before they're registered by evaluating the data that's generated.

Tr. April 1, p. 496.

Dr. Blackburn testified that she considered efficacy evaluations always important, but that they are especially important when the product is meant to be used in hospitals and food processing areas. *Id.* Dr. Blackburn explained:

> Well, in the food processing establishment your end product is going to be something that's going to be ingested, and it's important that proper products

> are used to mitigate public health organisms from getting in the food, from causing the diseases associated with food and by addressing the efficacy at the beginning of the process and knowing that the products that are to be used in these facilities are indeed efficacious, you can mitigate a lot of these infections or these pathologies.

Tr. April 1, pp. 496-497. As Respondent has pointed out, their lubricants are directed towards the food processing industry, and have been used by several large companies, including Kraft and Quaker Oats. R's Reply Brief, pp. 2-3.

Mr. Edwards also testified to the importance of efficacy testing of antimicrobial products. He stated that if a product did not live up to its claims, "then at the very least you could end up with cross-contamination, with whatever the public health organism is, going from one site to the other. And then the worst, you could end up with somebody at some point getting sick." Tr. April 1, p. 250. Dr. Blackburn testified as to the serious illnesses associated with Listeria, E.coli, and Salmonella that could occur if food contaminated with the bacteria was consumed by humans. Salmonella causes gastroenteritis, which in some instances, can result in death for the elderly, infants, immunocompromised, and immunosuppressed individuals. Tr. April 1, p. 470-471. Dr. Blackburn explained that E.coli can also cause gastroenteritis, as well as gram-negative pneumonia, meningitis, septicemia, mastisis, and urinary tract infections. Septicemia can also cause death. Meningitis is the inflammation of the brain lining, and can also cause death. *Id.* at 472-473. Listeria also causes gastroenteritis, septicemia, meningitis, and spontaneous abortions. *Id.* at 474. Dr. Blackburn's testimony as to the deadly effect of these bacteria demonstrates the importance of regulatory oversight of antimicrobial products in order to evaluate the truth of their antimicrobial claims, thereby preventing exposure of the public to the risk of disease.

In support of a lower penalty, Respondent states that Behnke has always sold its antimicrobial lubricants in compliance with FDA requirements under the FFDRA, and argues that therefore, the potential harm to the public was nominal. R's Reply Brief, p. 12. Respondent's argument ignores the fact that the FDA and EPA have different goals and requirements. While Behnke's lubricants are food additives within the FDA's regulations, this does not mean the lubricants were tested under EPA efficacy evaluation standards for their effect on bacteria. In fact, Dr. Blackburn testified that the FDA's guidance document (R's Ex. 53) could not serve as a substitute for the EPA guidelines on efficacy evaluations. Tr. April 2, p. 538. Dr. Blackburn points out that the FDA's guidance document does not have a set performance standard or go into the level of detail regarding testing requirements that the EPA does. *Id.* While Behnke's lubricants may be safe as food additives under the FDA, they still ran the risk of not living up to their bacteria-killing claims and thus exposing the public to deadly bacteria.

Respondent contends that Behnke and other third parties (such as Kraft) tested the lubricants to determine the efficacy of the lubricants in targeting microbes. R's Reply Brief, p. 12; Tr. April 3, pp. 775-778. Dr. Blackburn reviewed the lab test results on JAX Poly-Guard

FG-2 published by Respondent in some of its promotional material (C's Ex. 8c). Dr. Blackburn testified that the information provided was insufficient to evaluate the efficacy of the antimicrobial properties of the lubricant. Tr. April 2, p. 515. Dr. Blackburn noted that:

> [T]he data is silent on what test was actually conducted to generate the data. It's silent on the conduct, the study conduct, were the necessary controls present, what the contact time was for the products to be in contact with the surface, exposure time, the actual test organisms...I don't know what yeast colonies, what mold colonies they're referring to, what test organisms were tested. And the test method against is not present on any of these documents. The study conduct is missing as well.

Tr. April 2, pp. 515-516. Because of the missing information, Dr. Blackburn did not consider the data reliable. Tr. April 2, p. 516.

Therefore, I find that Respondent's argument that the potential harm to the public was nominal unpersuasive. Complainant has carried its burden of persuasion that the proposed penalty is appropriate in light of the gravity of the violation and the potential harm to the public.

The ERP

Under the ERP, the penalty is determined in a five stage process in consideration of Section 14(a)(4) criteria. These five steps are:

1. Determination of the gravity or "level" of violation using Appendix A of the ERP;

2. Determination of the size of business category for the violator, found in Table 2 of the ERP;

3. Use of the FIFRA civil penalty matrix found in Table 1 of the ERP to determine the dollar amount associated with the gravity level of the violation and the size of the business category of the violator;

4. Further Gravity Adjustments of the base penalty in consideration of the specific characteristics of the pesticide involved, the actual or potential harm to human health and/or the environment, the compliance history of the violator, and the culpability of the violator, using the "Gravity Adjustment Criteria" found in Appendix B of the ERP; and

5. Consideration of the effect that payment of the total civil penalty will have on the violator's ability to continue in business, in accordance with the criteria established in the ERP.

C's Ex. 33 at 18.

In order to determine of the final gravity of the violation under the ERP, a two part process is followed. First, the appropriate gravity "level" of the violation is determined. Second, the base penalty figure is adjusted, as determined from the gravity "level," to consider the actual set of circumstances that are involved in the violation. C's Ex. 33 at 21.

Base Gravity Level

Under Appendix A, the FIFRA ERP classifies a violation of 12(a)(1)(A) (distribution or sale of an unregistered pesticide) as a "Level 2" violation. C's Ex. 33 at A-1. I find that Complainant has correctly assigned a Level 2 violation to each of the 11 illegal distributions alleged in the Compliant.

Size of Business Category

As discussed above under the statutory factor, Complainant obtained a Dun & Bradstreet Report, printed June 6, 2006, that indicated that Behnke Lubricants Inc. had a sales volume of over $7,900,000. C's Ex. 14b. Complainant correctly placed Respondent in "Business Category I" as a respondent who is alleged to have violated Section 14(a)(1) of FIFRA and whose gross revenues/sales exceed $1 million.[8] C's Ex. 33 at 20; C's Post-Hearing Brief, p. 123. As previously stated, Respondent does not challenge this aspect of the penalty calculation. R's Post-Hearing Brief pp. 16-17.

Civil Penalty Matrix

The EPA used the ERP's Civil Penalty Matrix to assign a base penalty relative to the gravity of the violation and the size of the business. Each cell of the Civil Penalty Matrix represents the Agency's assessment of a penalty, within the statutory maximum considering each level of gravity of the violation and each size of the business category. Under the ERP, the base penalty assigned to a violation with a Level 2 Base Gravity Level and Business Category I is $5,000 (the original statutory maximum). Finally, following the Debt Collection Improvement Act of 1996, 40 C.F.R. part 19 and the EPA memorandum, "Penalty Policy Supplements Pursuant to the 2004 Civil Monetary Penalty Inflation Adjustment Rule," the EPA arrived at an adjusted base penalty of $6,500 per violation. C's Post-Hearing Brief, p. 124.

Gravity Adjustment Criteria

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[8]ERP Table 2 divides FIFRA Section 14(a)(1) violators (registrants, wholesalers, distributors) into three business size categories. Category I are businesses with over $1,000,000 in gross revenues in the prior calendar year, Category II applies to businesses with prior year gross revenues from $300,001 to $1,000,000, and Category III are businesses with gross revenues at or below $300,000. C's Ex 33 at 20; Tr. March 31, p. 189.

Next, the EPA applied the Gravity Adjustment Criteria to the base penalty of $6,500. The ERP lists gravity adjustment criteria for each violation relative to the specific characteristics of the pesticide involved, the harm to human health, and/or harm to the environment, compliance history of the violator, and the culpability of the violator. The gravity adjustment values from each gravity category from Appendix B are added together (up to a maximum total value of 21) and based upon Table 3 in the ERP, the gravity based penalty is either assessed as is, raised, or lowered. If the sum of the adjustment factors is 7 or below, the penalty is reduced or possibly eliminated. If the sum of the adjustment factors is between 8 to 12, the base penalty is assessed, and if the sum of adjustments is 13 or higher, the penalty is increased. C's Ex. 33, Appendix B, Table 3.

The ERP provides two choices for toxicity, either "1" or "2". Pesticides rating a "1" are those in Toxicity Categories II through IV, pesticides assigned the signal word "warning" or "caution" and those with no known chronic health effects. Pesticides rating a "2" are Toxicity Category I pesticides, pesticides requiring the signal word "danger", restricted use pesticides, pesticides that are flammable or explosive, or that cause chronic health effects. C's Ex. 33, Appendix B. Complainant has assigned a "pesticide" toxicity value of "1", based on the labels and advertisements, as the products were thought to be "food grade" and not toxic in themselves. C's Post-Hearing Brief, p. 125.

The EPA has also assigned a value of "1" to "harm to human health." C's Post-Hearing Brief, p. 125. The value of "1" means that the product represents "minor potential or actual harm to human health, neither serious nor widespread." C's Ex. 33 at B-1. Complainant has assigned a value of "1" to "harm to the environment." C's Post-Hearing Brief, p. 125. The value of "1" means the violations' potential for harm to the environment was minor, neither widespread nor substantial. C's Ex. 33 at B-1. These assignments were made at the initial filing of the Complaint. Based on testimony at the hearing, especially Dr. Blackburn's testimony, the EPA believes it could justify a higher assessment, but has elected not to depart from its original calculation. C's Post-Hearing Brief, p. 125.

Gravity of Misconduct includes "compliance history" and "culpability." C's Ex. 33, Appendix B. The EPA has assigned "compliance history" a value of zero, based on the absence of any record of any prior FIFRA violations by Respondent. C's Post-Hearing Brief, p. 126. I find that a "compliance history" value of zero is appropriate in this matter.

The EPA assigned "culpability" a value of "2", based on unknown culpability of the Respondent. Complainant believes that testimony adduced at the hearing would support a higher "culpability" level, but chooses to keep its original penalty calculation. C's Post-Hearing Brief, p. 126. Complainant points to the testimony regarding Respondent's communications with the NSF, in which the NSF told Respondent to register their product with the EPA as evidence that the violation was knowing and willful. Tr. March 31, pp. 190-195. The EPA also cites Respondent's continued violations even after the filing of the Complaint. C's Post-Hearing Brief, p. 126.

Respondent argues that the level "2" culpability assigned to it is incorrect. Instead, Respondent states that it should receive a level "0" culpability level. R's Post-Hearing Brief, p. 17. A level "0" culpability level is appropriate when "the violation was neither knowing nor willful and did not result from negligence. Violator instituted steps to correct the violation immediately after discovery of the violation." C's Ex. 33, at B-2. Respondent asserts that it attempted to comply with the EPA and NSF recommendations to the best of its ability. Respondent also stated that "it was only when Behnke believed that NSF and EPA's requests went too far that Behnke objected by asserting its legal rights." R's Reply Brief at 13. In regard to the violations committed after the Complaint was filed, Respondent argues that it should not be penalized for what it describes as "defending it good-faith interpretation of the law." R's Reply Brief, p. 13.

At the hearing, Mr. Bonace testified that in order to earn a culpability value of "0", the Respondent "would have had to taken steps to correct the violation and not - and the violation could not have been knowing." Tr. March 31, p. 195. While I am not penalizing Respondent in any way for seeking to go to hearing in this matter, the record before me does not support the finding that Respondent took steps to correct the violation and that the violation was unknowing. Therefore, I find Respondent's argument for a "0" culpability level unpersuasive.

Complainant's Calculation of the Total Penalty

At the next step, the EPA added together the values it had assigned to the five adjustment factors of pesticide toxicity (1), human harm (1), environmental harm (1), compliance history (0), and culpability (2), and obtained a Total Gravity Adjustment Value total of "5" for each violation. Under Table 3 of the ERP, a Total Gravity Adjustment Value of "5" means a reduction of the matrix value by 30 %. C's Ex. 33, p. 22. As each violation was initially assigned a matrix value of $6,500, the adjusted penalty for each violation is $4,550. Multiplying $4,550 by 11, the number of distributions, Complainant calculated a total proposed penalty of $50,050. C's Post-Hearing Brief, p. 126; C's Ex. 14a.

Ability to Continue in Business

As discussed above, the EPA considered the effect of the proposed penalty on Behnke's ability to continue in business through its financial analysis expert, Mr. Ewen of Industrial Economics. Mr. Ewen came to the conclusion, based on the available financial information, that Respondent could pay the proposed penalty. C's Ex. 32. The EPA considered a Dun & Bradstreet Report and a Waukesha County Tax Bill for the Behnke facility. Based on this information, the EPA determined that no reduction in the proposed penalty was necessary in order for Respondent to continue in business. C's Post-Hearing Brief, pp. 126-127. Again, Respondent waived any challenge to the proposed penalty based on ability to continue in business. R's Post-Hearing Brief pp. 16-17. Accordingly, no facts, testimony, or exhibits were introduced at the hearing regarding Respondent's inability to pay the proposed penalty of $50,050 because Respondent has affirmed that he is so able to pay.

Discussions and Conclusions as to Methodology and Penalty Assessment

I find that Complainant has calculated the proposed penalty in accordance with the Enforcement Penalty Policy for FIFRA and has taken into consideration all necessary statutory factors. However, under 40 C.F.R. § 22.27(b) an Administrative Law Judge has discretion to assess a penalty different in amount from the penalty proposed by the complaint, setting forth in the initial decision the specific reasons for the increase or decrease based on the evidence in the record and in accordance with the penalty criteria set forth in the applicable Act. The final assessment of civil penalties is committed to the informed discretion of the court. *See Catskill Mountains Chapter of Trout Unlimited, Inc. v. City of New York*, 451 F.3d 77, 87 (2nd Cir. 2006); *United States v. Gurley*, 384 F.3d 316, 324 (6th Cir. 2004); *reh'g denied* 2005 U.S. App. LEXIS 425 (6th Cir. January 6, 2005) (en banc).

Upon considering all the evidence, I find sufficient compelling reasons to depart from the EPA's calculation of the penalty in this case under the ERP. I agree with the EPA that the evidence produced at hearing supports a culpability level of "4."[9] Although EPA has chosen to stay with a culpability level of "2" in this case, I find that a culpability value of "4" should be assigned. A culpability level of "4" is assigned when there is a "knowing or willful violation of the statute. Knowledge of the general hazardousness of the action." C's Ex. 33 at B-2. Although the EPA has chosen to stay with its original penalty calculation, I find that a culpability level of "4" is more appropriate in this case.

Complainant has produced evidence that Respondent was warned by the NSF as early as 2003 that it was making antimicrobial claims that would require its products to be registered under FIFRA. C's Ex. 37; Tr. March 31, p. 194. Mr. Peter, the president of Behnke, admitted at the hearing in regard to Behnke's labeling, that NSF "conveyed that they thought that this would be - possibly run amuck of some EPA pesticide concerns." Tr. April 2, p. 599. Mr. Peter also testified that "I was approached with a concern about the language on our labeling by NSF." Tr. April 2, p. 599. Mr. Peter and Mr. Paquette both did some research into EPA and FIFRA regulations themselves. Tr. April 2, p. 654. Respondent clearly was aware that it might be subject to EPA regulations and made a decision to go forward without so much as checking with the EPA for clarification. At the hearing, Mr. Bonace, an experienced enforcement specialist with EPA, testified that he did not have this information when he originally calculated the penalty, and based on it, he would propose that the culpability level be changed to a "4." Tr. March 31, p. 197.

Behnke made a conscious business decision that it would go forward with its sale of the lubricants without registering with the EPA. Mr. Peter admitted at the hearing that "we did not want to be listed under FIFRA" (Tr. April 2, p. 653) and that "[w]e wanted to stay out of that bailiwick." Tr. April 2, p. 669. Mr. Peter testified that he did not want the lubricants to require FIFRA registration because of:

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[9]The ERP provides culpability levels of 0, 2, and 4 only. C's Ex. 33 at B-2.

> [T]he extensive and extremely expensive processes to go through to get these types of approvals and the subsequent possible state approvals, the different things there were needed. So we took the tact that we would, at all costs, do our best job to avoid language that would implicate us in FIFRA labeling and try and stay within the language that was given to us in the FDA guidelines.

Tr. April 2, p. 622. Mr. Peter also testified that having EPA registration would cause Behnke to lose its competitive edge over its competitors in the marketplace. Tr. April 2, p. 672. Mr. Peter admitted that selling its lubricants without EPA registration was a business decision. Tr. April 2, p. 673. He stated that he was willing to take the risk that EPA would eventually contact him in regard to the lubricants. *Id.*

Although the NSF pointed out that pesticidal claims on their lubricants could concern the EPA in 2003, Mr. Peter testified he did not contact the EPA to inquire if the lubricants needed to be registered with the EPA as a pesticide. Tr. April 2, p. 665. Mr. Peter attended a trade group annual meeting at which the EPA's Mr. Edwards gave a presentation on EPA registration of treated materials. Mr. Peter testified that he spoke with Mr. Edwards after the presentation but did not ask him any questions regarding Behnke's lubricants being subject to FIFRA registration. Mr. Peter also did not try to schedule a meeting with Mr. Edwards to clarify his understanding of EPA regulations. Mr. Peter testified that this was another business decision. Tr. April 2, pp. 686-694. After Mr. Saatkamp inspected Respondent's facility, Respondent still made a conscious business decision not to contact the EPA. Tr. April 2, pp. 673-674. Respondent's longstanding indifference to the applicable FIFRA regulations, given its long experience as a business operating in federally regulated arenas aggravates his culpability.

Even after the EPA filed a Complaint against Respondent, it continued to sell or distribute its unregistered pesticide products. Mr. Bonace testified that on the very first day of the hearing he checked Respondent's website and found that Behnke was still making pesticidal claims. Tr. March 31, p. 195. Almost one year after Respondent became aware of the Complaint and was notified that it was allegedly violating the federal regulations Respondent was still making pesticidal claims on its website. It was only after the first day of the hearing that Mr. Peter made sure that those claims were taken off of Behnke's website. Tr. April 2, p. 631. Respondent is culpable for avoiding its regulatory responsibilities under FIFRA, a behavior that is unacceptable and conflicts with the goals and undermines the purposes of the FIFRA. Based on the record before me, I find that a culpability level of "4" is appropriate in this matter.

Adding together the values assigned to the five adjustment factors of pesticide toxicity (1), human harm (1), environmental harm (1), compliance history (0), and culpability (4), I obtain a Total Gravity Adjustment Value total of 7 for each violation. Under Table 3 of the ERP, a Total Gravity Adjustment Value of "7" means a reduction of the matrix value by 10 %. C's Ex. 33, p. 22. As each violation was initially assigned a matrix value of $6,500, the adjusted penalty for each violation is $5,850. Multiplying $5,850 by 11, the number of distributions, the total

penalty warranted is $64,350. Nonetheless, I am capping the increase to 10% of the total proposed penalty, resulting in an assessed penalty of $55,055.

Given the seriousness of these violations, I find a $55,055 penalty reasonable and appropriate. This figure is deemed appropriate in light of the three statutory factors set forth in FIFRA Section 14(a)(4) and the ERP as discussed in more detail above.

ORDER

1. Respondent Behnke Lubricants, Inc. is assessed a civil administrative penalty in the amount of $ 55,055.

2. Payment of the full amount of this civil administrative penalty shall be made within thirty (30) days after this Initial Decision becomes a final order under 40 C.F.R. § 22.27(c), as provided below.[10] Payment shall be made by submitting a certified or cashier's check in the

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[10]Alternatively, Respondent may make payment of the penalty as follows:

WIRE TRANSFERS:

Wire transfers should be directed to the Federal Reserve Bank of New York

Federal Reserve Bank of New York
ABA = 021030004
Account = 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York NY 10045
Field Tag 4200 of the Fedwire message should read " D 68010727 Environmental Protection Agency "

OVERNIGHT MAIL:

U.S. Bank
1005 Convention Plaza
Mail Station SL-MO-C2GL
St. Louis, MO 63101

Contact: Natalie Pearson
314-418-4087

ACH (also known as REX or remittance express)

amount of $55,055, payable to "Treasurer, United States of America," and mailed to:

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

3. A transmittal letter identifying the subject case title and EPA docket number (FIFRA 05-2007-0025), as well as Respondent's name and address, must accompany the check.

4. If Respondent fails to pay the penalty within the prescribed statutory period after entry of the Order, interest on the civil penalty may be assessed. 31 U.S.C. § 3717; 31 C.F.R. §§ 13.11, 901.9.

APPEAL RIGHTS

This Order constitutes an Initial Decision as provided in Section 22.17(c) of the Rules of Practice, 40 C.F.R. 22.17(c). Pursuant to Sections 22.17(c) and 22.30 of the Rules of Practice, 40 C.F.R. §§ 22.27(c) and 22.30, this Initial Decision shall become the Final Order of the Agency

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Automated Clearinghouse (ACH) for receiving US currency

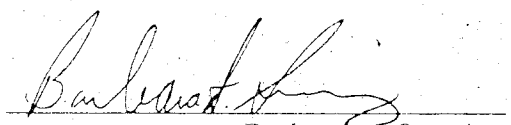
PNC Bank
808 17th Street, NW
Washington, DC 20074
Contact – Jesse White 301-887-6548
ABA = 051036706
Transaction Code 22 - checking
Environmental Protection Agency
Account 310006
CTX Format

ON LINE PAYMENT:

This payment option can be accessed from the information below:
WWW.PAY.GOV
Enter sfo 1.1 in the search field.
Open form and complete required fields.

unless an appeal is filed with the Environmental Appeals Board within thirty (30) days of service of this Order, or the Environmental Appeals Board elects, *sua sponte*, to review this decision.

Copies of this Order, the Initial Decision, dated December 30, 2008, are being served on both parties, as well as the Regional Hearing Clerk, in accordance with 40 C.F.R. § 22.27(a). However, this Initial Decision is not being released or made available to the public at this time, but will be publicly released on January 14, 2009, barring any persuasive objections. If either party objects to the Initial Decision on the basis of containing confidential business information ("CBI"), such objection must be served on the undersigned no later than January 12, 2009. The parties are reminded that the delayed public release of this Initial Decision does not affect the appeal period specified in 40 C.F.R. § 22.30.



Barbara A. Gunning
Administrative Law Judge

Dated: December 30, 2008
Washington, D.C.

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

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **INITIAL DECISION**, dated December 30, 2008, was sent this day in the following manner to the addressees listed below.

Mary Angeles
Legal Staff Assistant

Original and One Copy by Pouch Mail to:

Tywanna Greene
Acting Regional Hearing Clerk
U.S. EPA, Region V, MC-13J
77 West Jackson Blvd., 13th Floor
Chicago, IL 60604-3590

Copy by Certified Pouch Mail to:

Nidhi K. O'Meara, Esq.
James J. Cha, Esq.
Erik H. Olson, Esq.
Associate Regional Counsels
U.S. EPA, Region V, C-14J
77 West Jackson Boulevard
Chicago, IL 60604-3590

Copy by Certified Mail to:

Bruce A. McIlnay, Esq.
Linda S. Isnard, Esq.
Joseph F. Kirgues, Esq.
McIlnay & Button, Ltd.
1150 Washington Street
Grafton, WI 53024

Dated: December 30, 2008
Washington, D.C.

ATTACHMENT A

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
BEHNKE LUBRICANTS, INC.,	)	DOCKET NO. FIFRA-05-2007-0025
	)	
	)	
RESPONDENT	)	

ORDER DENYING COMPLAINANT'S MOTION TO STRIKE RESPONDENT'S AFFIRMATIVE DEFENSES; ORDER GRANTING, IN PART, AND DENYING, IN PART, COMPLAINANT'S MOTION TO COMPEL DISCOVERY; ORDER DENYING COMPLAINANT'S MOTION FOR ACCELERATED DECISION ON LIABILITY AND ON AFFIRMATIVE DEFENSES

On May 7, 2007, the United States Environmental Protection Agency ("the EPA"), Region V ("Complainant" or "the Region"), filed an eleven-count civil administrative Complaint against Behnke Lubricants, Inc. ("Respondent" or "Behnke") pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended, 7 U.S.C. § 136*l*(a), for the assessment of a civil penalty. Complainant alleges that on at least eleven different instances, Respondent distributed or sold various unregistered pesticides in violation of Sections 3(a) and 12(a)(1)(A) of FIFRA, 7 U.S.C. §§ 136a(a) and 136j(a)(1)(A). Complainant proposes a civil administrative penalty of $50,050. Respondent filed its Answer and Request for Hearing ("Answer") on or about June 8, 2007. This proceeding is governed by 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. §§ 22.1-.32.

The undersigned entered a Prehearing Order on June 27, 2007, which, *inter alia*, set a schedule for the prehearing exchange. The parties have filed their prehearing exchange in this matter and reserved the right to supplement their prehearing exchange

and supplemental prehearing exchange.[1] The undersigned entered an Order Scheduling Hearing on January 14, 2008. The Hearing in this matter has been scheduled for Monday, March 31, 2008 commencing at 9:30 a.m. and to continue as found necessary through Friday, April 11, 2008, commencing at 8:30 a.m., excluding Wednesday, April 9, 2008, at the Waukesha County Courthouse in Waukesha County, Wisconsin. *See* 40 C.F.R. § 22.35(b).

I. Complainant's Motion to Strike Affirmative Defenses and Complainant's Motion to Compel Discovery

A. Procedural Background

On January 16, 2008, Complainant filed Complainant's Motion to Strike Affirmative Defenses ("Motion to Strike"), and Complainant's Motion to Compel Discovery ("Motion to Compel"). *See* 40 C.F.R. §§ 22.16(a) and 22.19(e).[2] Complainant's Motion to Strike requests that the undersigned strike four of the defenses Respondent lists as "affirmative defenses" on pages 27-28 of its Answer.[3] In particular, Respondent asserts the following as its "affirmative defenses": (1) Behnke's products are not "pesticides" within the meaning of 7 U.S.C. § 136(u); (2)

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[1] The parties are reminded that Sections 22.19(a) and 22.22(a) of the Rules of Practice provide that documents or exhibits that have not been exchanged and witnesses whose names have not been exchanged at least fifteen (15) days before the hearing date shall not be admitted into evidence or allowed to testify unless good cause is shown for failing to exchange the required information.

[2] Although Complainant has submitted these two motions within a single motion, the arguments for each are presented in distinct and separate sections of the motion. Thus, for ease of reference I assign each motion its own shorthand designation.

[3] In this motion, Complainant notes that it is unclear whether each of Respondent's asserted defenses in fact meet the standard for "affirmative defenses," yet nevertheless states, "For simplicity, Complainant will refer to these defenses as 'affirmative defenses' in the instant motion." *See* Mot. to Strike at n.1. I decline to take the same approach and will instead hereafter refer to Respondent's purported "affirmative defenses" as "defenses/affirmative defenses."

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) that are approved as lubricants with incidental food contact pursuant to 21 C.F.R. § 178.3570, a regulation promulgated pursuant to 21 U.S.C. § 348(a), which means Behnke's products are strictly regulated by the Food and Drug Administration ("FDA") 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, so Behnke's products are formulated to protect themselves, by resisting internal degradation, from contaminants found in food processing environments; and (7) Behnke's products are not intended for a pesticidal purpose as set forth in 40 C.F.R. § 152.15, because a "pest" as defined in 40 C.F.R. § 152.5 does not include the microorganisms on or in processed food to which Behnke's products are exposed. Answer at 27-28.

Specifically, Complainant moves to strike Respondent's defenses/affirmative defenses 3, 4, 5, and 6 as legally insufficient defenses against liability. Mot. to Strike at 11. Thus, Complainant asserts that "[i]t is therefore unnecessary for this Court to engage in the time-consuming task of fact-finding in an evidentiary hearing on these defenses . . . [as they do not] have any legal affect on Respondent's liability for the violations of FIFRA alleged in the Complaint." *Id.* at 13.

With regard to Respondent's third defense/affirmative defense, Complainant argues that whether or not Behnke's products meet the definition of "antimicrobial pesticide" under FIFRA Section 2(mm) has no bearing on whether such products are "pesticides" within the meaning of FIFRA because "antimicrobial pesticides" are still subject to FIFRA registration; the potential designation of a product as an "antimicrobial pesticide" simply expedites review of the product's FIFRA registration application under FIFRA Section 3(h). *Id.* at 15-21. With regard to Respondent's fourth defense/affirmative defense, Complainant argues that whether or not Behnke's products are "pesticide chemicals" within the meaning of 21 U.S.C. § 321(q)(1)(A) has absolutely no bearing on whether the products are "pesticides" under FIFRA because the EPA's jurisdiction under the FFDCA is separate and distinct from the EPA's jurisdiction under FIFRA. *Id.* at 21-26. With regard to Respondent's fifth defense/affirmative defense, Complainant argues that, like the

"pesticide chemical" argument asserted in Respondent's fourth defense/affirmative defense, whether or not Behnke's products are "food additives" within the meaning of 21 U.S.C. § 321(s) that are regulated under the FFDCA does not affect whether the products are likewise "pesticides" regulated under FIFRA. Mot. to Strike at 26-29. Finally, with regard to Respondent's sixth defense/affirmative defense, Complainant interprets Respondent's language as implying that Behnke's products fall within the "Treated articles or substances" exemption set forth in FIFRA's implementing regulations at 40 C.F.R. § 152.25(a), and Complainant argues that even if this exemption applies, Behnke's Lubricants are still subject to FIFRA registration because the exemption requires that the article or substance at issue must contain, or have been treated with, a pesticide that has been registered under FIFRA for use in protecting the article or substance. *Id.* at 29-30.

Complainant's Motion to Compel seeks discovery in connection with Respondent's defenses/affirmative defenses 1, 2, and 7. Mot. to Compel at 30. Additionally, the Motion to Compel instructs that should the Motion to Strike be denied, Complainant moves in the alternative for discovery in connection with Respondent's defenses/affirmative defenses 5 and 6.[4] *Id.* Complainant argues that the undersigned should grant the discovery requests because the information sought is "required for Respondent to support its affirmative defenses." *Id.*

Specifically, Complainant requests eighteen categories of information, simplified in summary form as follows:

> (1) true, accurate and complete copies of all documentation or communication from and/or to any federal, state or local agency or authority relating to Behnke's lubricants, JAX Poly-Guard FG-2, JAX Halo-Guard FG-2, JAX Magna-Plate 78, JAX Magna Plate 74, JAX Halo-Guard FG-LT and JAX Poly-Guard FG-LT ("Behnke's Lubricants"), or concerning any lubricant containing Micronox;
> (2) a complete and accurate list of the chemical components of Behnke's Lubricants, by chemical name and by C.A.S. number;

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[4] Complainant is not seeking discovery of the information that it previously requested on June 21, 2007, in connection with Respondent's Affirmative Defenses 3 and 4. Mot. to Compel at n.8. Complainant maintains that information relating to these defenses cannot have any relevance to the issues presented in the instant case. *Id.*

(3) true, accurate and complete copies of all documents that specifically describe the intended uses of Behnke's products;
(4) a complete and detailed explanation, with substantiating documents, supporting Respondent's assertion that Behnke's products are strictly regulated by the Food & Drug Administration;
(5) true, accurate and complete copies of all documents containing evidence that any of Behnke's products at issue in this case were approved as lubricants with incidental food contact, including all notifications submitted to FDA or the Department of Health and Human Services ("DHHS") regarding Behnke's Lubricants;
(6) true, accurate and complete copies of all documents containing information about the identity and intended use of the lubricant/food contact substance, and Behnke's determination that such intended use was safe in accordance with Section 409(c)(3)(A) of the FFDCA;
(7) a complete and accurate statement explaining how Behnke's Lubricants can be safely used on machinery that is used for packing, manufacturing, processing, preparing, treating, packaging, transporting, or holding food;
(8) A statement specifying whether each of Behnke's Lubricants can be used safely because the lubricants are prepared from substances that are either generally recognized as safe for use in food, that are used in accordance with the provisions of a prior sanction or approval, or that are identified in 21 C.F.R. Section 178.3570(a)(3);
(9) a statement identifying the specific substance in each lubricant that fall in each category listed in the previous category of information requested, category 8;
(10) true, accurate and complete copies of all documentation and communications between Behnke and NSF International regarding any Behnke lubricants containing Micronox, and true, accurate and complete copies of all documents submitted by or on behalf of Behnke to NSF in connection with NSF's completion of its evaluation requirements for Behnke's Lubricants;
(11) a statement identifying how Behnke's Lubricants are formulated to resist internal degradation from contaminants found in food processing environments;
(12) a statement specifically identifying the contaminants that Behnke is referring to in its defense/affirmative defense number 6, and if such contaminants are microorganisms, an explanation as to how Behnke complied with the treated article exemption pursuant to 40 C.F.R. Section 152.25;

(13) a statement identifying the antimicrobial additive that is in each of Behnke's Lubricants, by chemical name, C.A.S. number, and EPA Registration number;
(14) a statement providing context for Respondent's prehearing exchange exhibit number 54 ("Behnke Publication regarding food grade lubricant certification");
(15) a statement as to whether Respondent intends to contest the amount of the proposed penalty, and if so, explaining in detail why and how Respondent believes the proposed penalty should be reduced or eliminated;
(16) true, accurate and complete copies of documents that show the actual gross sales or revenues of Behnke Lubricants, Inc., or a statement expressly waiving any objection to the penalty based on the "size of business" statutory penalty factor in Section 14(a)(4) of FIFRA, 7 U.S.C. § 136*l*(a)(4);
(17) a statement clarifying the relationship between Xact Fluid Solutions and Behnke; and
(18) revised narrative summaries of the expected testimony of Respondent's witnesses, inclusive of information and documents specifically requested in connection with each witness.

Mot. to Compel at 36-50. Complainant asserts that it makes the instant motion for this additional discovery in response to Respondent's failure to provide substantial evidence in support of its affirmative defenses in its prehearing exchange. *Id.* at 32-33.

On February 5, 2008, Respondent filed Respondent's Response to Complainant's Motion to Strike Respondent's Affirmative Defenses and Motion to Compel Discovery ("Response to Motions to Strike and Compel"). *See* 40 C.F.R. § 22.16(b). In support of its defenses/affirmative defenses, Respondent sets forth its contention that there are, among other disputed issues of fact, four primary issues of disputed fact in this matter: (1) whether its products are, in fact, "pesticides" within the meaning of FIFRA § 2u, 7 U.S.C. § 136(u), or are otherwise exempt from FIFRA regulation; (2) whether Behnke's Lubricants are "intended" for preventing, destroying, repelling, or mitigating any pest within the meaning of FIFRA § 2u; (3) whether Behnke's Lubricants "destroy, repel or mitigate" any "pest" within the meaning of FIFRA and its implementing regulations; and (4) whether Behnke's Lubricants are "food additives" subject to regulation under 21 U.S.C. § 348, *et seq.*, designated as such by the FDA. Resp. to Mots. to Strike and Compel at 3-7. In essence, Respondent argues that Behnke's Lubricants are intended to protect components of equipment in food and beverage manufacturing plants and are