THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN VANGUARD CORPORATION,	)	
	)	
Plaintiff,	)	
	)	**Case No. 1:10-cv-01459**
v.	)	
	)	
LISA P. JACKSON, *et al.*	)	
	)	
Defendants.	)	

PLAINTIFF'S BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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Plaintiff American Vanguard Corporation ("AMVAC") submits this brief in support of its motion for summary judgment.

I. INTRODUCTION

AMVAC seeks to vacate and to enjoin enforcement of an August 12, 2010 Stop Sale, Use, and Removal Order ("SSURO") issued by the Environmental Protection Agency ("EPA") under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. The SSURO is directed at all products sold under AMVAC's FIFRA Registration No. 5481-197 for "Technical Grade PCNB" product (the "Registration"). The SSURO effectively revokes the Registration that has been in effect since 1985 and that authorizes the distribution and sale of the product. The PCNB product targeted by the SSURO is the same product that has been approved three times by EPA over the last three decades. The SSURO is currently destroying over $20 million in annual business that AMVAC cannot recover should it be vacated by the Court.[1]

The SSURO was issued without prior notice or opportunity to be heard. It requires AMVAC immediately to cease selling, and to propose a plan to collect and destroy, all products sold under the Registration. FIFRA does not permit EPA to use a SSURO to bypass the specific statutory procedures required to be followed if the agency wants to suspend all sales under a valid registration or demand that the registration be cancelled or amended. Even if FIFRA did permit such use of a SSURO, the Administrative Procedure Act and the Fifth Amendment to the U.S. Constitution preclude EPA from revoking AMVAC's Registration, which is a license and protected property interest, without prior notice and opportunity to be heard.

[1] AMVAC is currently losing millions of dollars because it is prohibited from selling its registered product during the principal period of time that it is sold and used. On September 2, 2010, the Honorable Richard Roberts, sitting as emergency motions judge, denied AMVAC's motion for a temporary restraining order ("TRO") in this matter. AMVAC subsequently agreed to consolidate the preliminary injunction hearing with the merits, on an expedited schedule.

Improper revocation of AMVAC's Registration aside, EPA's decision to issue the SSURO is also arbitrary, capricious and inconsistent with law. EPA alleges that AMVAC failed to include in the Confidential Statement of Formula ("CSF") for the product a reference to trace amounts of an impurity — Impurity X.[2] It is undisputed, however, that (a) AMVAC disclosed the presence of Impurity X to EPA in 1993; (b) EPA reviewed and acknowledged that Impurity X was present; and (c) on at least three occasions following receipt of AMVAC's disclosure, EPA approved the Registration without requiring that the CSF identify Impurity X. These approvals by EPA constitute affirmative determinations that AMVAC's PCNB product, as manufactured and described in the CSF, and containing Impurity X, was in full compliance with FIFRA even if Impurity X was not identified in the CSF.

There is no proper record to support the SSURO. Moreover, what was offered by the Agency as the "record" contains no explanation for why EPA, after receiving AMVAC's 1993 submission and approving the Registration for the product on three subsequent occasions without requiring identification of Impurity X in the CSF, now reverses itself and imposes its new decision retroactively. Nor does the record contain a determination by EPA that Impurity X is, in connection with this product, "toxicologically significant." Without that determination, there is no requirement under the applicable regulation to list Impurity X on the CSF, and no basis for EPA to require an amendment to the existing product registration. Moreover, even if EPA could simply declare the approved CSF for this product inadequate without using the procedures

[2] As indicated by EPA's SSURO, the identity of Impurity X is protected as confidential business information. As such, it has not been identified in AMVAC's filings with the Court. To the extent it is necessary to identify Impurity X, it is done so in documents filed under seal by consent of the parties. It is undisputed that this impurity is neither an active ingredient nor necessary for the product, but rather is unintentionally created in the manufacturing process.

established by FIFRA, the absence of such a determination means that there is no violation upon which the SSURO can be based. The SSURO must be vacated.

II. REGULATORY BACKGROUND AND UNDISPUTED FACTS

A. Regulatory Background.

1. Registration.

FIFRA requires that each pesticide to be sold or distributed in any state must first be registered with EPA. 7 U.S.C. § 136a(a). To obtain a registration under FIFRA, an applicant must submit, *inter alia*, a complete copy of the labeling for the pesticide, the complete formula of the pesticide, and a full description of all the data that support its registration. 7 U.S.C. § 136a(c)(1). EPA is required to "publish guidelines specifying the kinds of information that will be required to support registration." 7 U.S.C. § 136a(c)(2)(A). The general data requirements for registration are set forth in 40 C.F.R. Part 158. If EPA determines that additional data are required to support one or more existing pesticide registrations, EPA may issue a "data call in" requiring that all affected registrants develop and submit such additional data. 7 U.S.C. § 136a(c)(2)(B).

To approve a pesticide registration, EPA must make certain specific determinations regarding the pesticide, including that:

> (A) its composition is such as to warrant the proposed claims for it;
> (B) its labeling and other material required to be submitted comply with the requirements of this subchapter [7 U.S.C. §§ 136 to 136y];
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(5). "Unreasonable adverse effects on the environment" is further defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and

environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb). Thus, to register a pesticide, EPA must evaluate and balance the risks and benefits associated with its use.

2. Confidential Statement of Formula.

In general, each registered product must have a "single defined composition," 40 C.F.R. § 152.43(a), which is known as a Confidential Statement of Formula ("CSF"). Specific information on product identity and composition must be included in the CSF, including the active ingredient, any inert ingredients, and certain types of impurities. 40 C.F.R. § 158.320. Not every impurity in a pesticide must be identified in the CSF. Rather, an impurity associated with the active ingredient must be listed in the CSF if it has been found in any sample of the active ingredient at a level greater than or equal to 0.1 percent by weight, 40 C.F.R. §§ 158.320(d), or, as relevant to this case, has been "determined by EPA to be toxicologically significant." 40 C.F.R. § 158.320(c). That regulation provides in pertinent part:

> (c) Impurities of toxicological significance associated with the active ingredient. For **each impurity associated with the active ingredient that is determined by EPA to be toxicologically significant**, the following information is required …:

40 C.F.R. § 158.320(c) (emphasis added). This obligation is imposed on a registrant only after EPA has determined that the impurity is toxicologically significant. There is nothing in the applicable regulation requiring that EPA determine that any impurity that is present at a level less than 0.1 percent by weight is *not* of toxicological significance in order to omit it from the CSF.

3. Amended Registration.

If a registrant wishes to make "any modification in the composition, labeling, or packaging of a registered product," the registrant must submit an application for amended registration. 40 C.F.R. § 152.44(a). When an application for amended registration is required, the product as modified may not be legally sold or distributed until after the application for amended

registration has been specifically approved by EPA. 40 C.F.R. § 152.44(a). EPA's review of an application for amended registration must specifically determine that the product as amended will continue to meet the statutory criteria for registration established by FIFRA § 3(c)(5). 40 C.F.R. §§ 152.100(a) and 152.112.

4. Reregistration.

FIFRA was amended in 1988 to require that EPA review and "reregister" each pesticide containing an active ingredient first registered before November 1, 1984. 7 U.S.C. § 136a-1(a). As part of this reregistration process, registrants were required to identify any "missing or inadequate data," 7 U.S.C. § 136a-1(d)(3), and to develop and to submit all additional data required to support a reregistration decision. 7 U.S.C. § 136a-1(e)(2). EPA was required to conduct an "independent review" to determine if all necessary data had been submitted, 7 U.S.C. § 136a-1(f)(1), and to issue a "data call in" under FIFRA § 3(c)(2)(B) for any necessary data not previously identified and submitted by the registrants. 7 U.S.C. § 136a-1(f)(2).

Before making its reregistration decision for a given pesticide product, EPA was required to "conduct a thorough examination of all data submitted." 7 U.S.C. § 136a-1(g)(1). Based on this thorough review of all the data, EPA was then required to make a new determination whether that pesticide "meets the requirements of section 136a(c)(5)." 7 U.S.C. § 136a-1(g)(2)(C). The statutory determinations required to support reregistration thus were identical to the determinations required for initial registration. *See* Section II.A.1, *supra.* In addition, after completion of the reregistration process, EPA must do a periodic "registration review" at least every 15 years for pesticides that contain each active ingredient. 7 U.S.C. § 136a(g).

5. Submission of Additional Factual Information by Registrants.

In addition to any data that may be collected as part of the initial registration process, in response to a "data call in" under FIFRA § 3(c)(2)(B), as part of reregistration, or as part of

periodic registration review, each registrant also has an obligation at any time to submit "additional factual information regarding unreasonable adverse effects on the environment of the pesticide." 7 U.S.C. § 136d(a)(2). This statutory requirement has been interpreted by EPA to extend to virtually any information on risks or benefits of a registered pesticide that is obtained by a registrant.[3] If an applicant for registration has any information the submission of which would be required under FIFRA § 6(a)(2), that information must be submitted with the application. 40 C.F.R. § 152.50(f)(3).

If a registrant makes the submissions called for in FIFRA § 6(a)(2) in accordance with 40 C.F.R. Part 159, Subpart D, such compliance "will satisfy a registrant's obligations to submit additional information pursuant to section 6(a)(2) and will satisfy an applicant's obligation to submit additional information pursuant to § 152.50(f)(3) of this chapter." 40 C.F.R. § 159.152(c). Since the only application an existing registrant would be submitting for an already registered product is an application for amended registration, EPA rules clearly contemplate that submissions made by a registrant under FIFRA § 6(a)(2) for a particular product will be reviewed and considered as part of subsequent amendment applications.[4]

6. Cancellation and Suspension of Registrations.

If after registering a pesticide, EPA determines that the pesticide "does not comply with the provisions of this subchapter, or when used in accordance with widespread and commonly

[3] Because EPA does not consider all information on risks and benefits to be of equal regulatory significance, EPA has clarified and limited its policy on what information it wishes to be submitted under FIFRA § 6(a)(2) in a series of notices issued over the years. *See, generally*, 43 Fed. Reg. 37611 (Aug. 23, 1978); 44 Fed. Reg. 40716 (July 12, 1979); 50 Fed. Reg. 38115 (Sept. 20, 1985).

[4] This is confirmed by the data requirement rules that were in effect in 2005 (when AMVAC submitted an application for amended registration to adopt the current CSF for Technical PCNB), which specifically stated: "Data which previously have been submitted need not be resubmitted unless resubmission is specifically requested by the Agency." 40 C.F.R. § 158.32(e), as adopted at 53 Fed. Reg. 15991 (May 4, 1988).

recognized practice, generally causes unreasonable adverse effects on the environment," EPA may issue a notice of intent to cancel the registration of the pesticide under FIFRA § 6(b), 7 U.S.C. § 136d(b). EPA may also utilize this provision to compel an existing registrant to make "necessary corrections" in the labeling or other terms and conditions of registration, by affording the registrant the opportunity to make such changes in lieu of cancellation. 7 U.S.C. § 136d(b). Before issuing a cancellation notice, EPA must: (a) prepare an analysis of the impact of the proposed action on the agricultural economy for review and comment by the Secretary of Agriculture, 7 U.S.C. § 136d(b); and (b) submit the notice to the FIFRA Scientific Advisory Panel for comment on "the impact on health and the environment of the action." 7 U.S.C. § 136w(d).

If EPA issues a cancellation notice, the registrant or another person adversely affected by the notice may request a hearing in accordance with 40 C.F.R. Part 164. A pesticide cancellation hearing is a formal adjudication governed by 5 U.S.C. § 554, and the requestor has a number of important procedural rights, including discovery, cross-examination of all adverse witnesses, a hearing before an ALJ, and the right to appeal to EPA's Environmental Appeals Board, to the Administrator, and ultimately to a federal court, all of which occur before cancellation is effective. *See* 40 C.F.R. Part 164.

If EPA decides that action is necessary to prevent an imminent hazard from the registered pesticide before the cancellation is effective, EPA may issue a notice of intent to suspend a registration. 7 U.S.C. § 136d(c)(1). The registrant may request an expedited hearing on, among other things, whether there is an imminent hazard before the suspension is effective. 7 U.S.C. § 136d(c)(2). EPA may also issue an emergency suspension order if it determines that there is an

emergency that does not permit an expedited hearing on the question of imminent hazard before suspension is ordered. 7 U.S.C. § 136d(c).

7. Enforcement Actions.

a. Violations.

FIFRA § 12, 7 U.S.C. § 136j, defines a number of specific violations involving pesticide products that can result in enforcement action by EPA. In general, these defined violations will not occur for a registered pesticide which is being sold or distributed in compliance with the terms of its registration. This is because EPA must find that the product's "composition is such as to warrant the proposed claims for it" and "its labeling and other material required to be submitted comply with the requirements of [FIFRA]" before registration can even be granted. 7 U.S.C. §§ 136a(5)(A) & (B). For example, FIFRA states that pesticide products will be deemed "misbranded" in a variety of specific circumstances, 7 U.S.C. 136(q), but EPA must specifically find that a product is not misbranded under any of these definitions before registration can be granted. 40 C.F.R. § 152.112(f); *See also* n.15, *infra*.

The fact that a pesticide product is registered is not a defense to a violation, but registration is "prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of [FIFRA]." 7 U.S.C. § 136a(f)(2). Thus, a violation necessarily cannot be based on a fact or condition that EPA determined was appropriate under FIFRA § 3(c)(5) when it granted the registration.

b. Civil and Criminal Penalties.

When EPA determines that a specific violation of FIFRA has occurred, it has authority to seek civil or criminal penalties. EPA can issue a complaint seeking a civil penalty from a registrant, but such a penalty may be imposed only after notice and an opportunity for a hearing before an ALJ. 7 U.S.C. § 136*l*(a). EPA can also seek criminal penalties including imprisonment

through a judicial action if a registrant, applicant for registration, or producer knowingly violates FIFRA. 7 U.S.C. § 136*l*(b).

c. Stop Sale, Use, or Removal Orders.

FIFRA authorizes EPA to issue a SSURO when "any pesticide or device is found in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this subchapter." 7 U.S.C. § 136k(a). The FIFRA Enforcement Response Policy, adopted by the EPA Office of Enforcement and Compliance Assurance ("OECA") in December 2009, identifies five situations in which EPA "should issue a SSURO" and two additional situations where EPA "may issue a SSURO."[5] Unlike a proceeding for a civil or criminal penalty, or a suspension or cancellation proceeding, FIFRA does not expressly require notice or any opportunity for a prior hearing before issuance of a SSURO. *Id.* A SSURO is final agency action reviewable in U.S. District Court under FIFRA § 16(a), 7 U.S.C. § 136n(a).

B. Undisputed Facts.

AMVAC manufactures, distributes, and sells a variety of agricultural products, including herbicides, insecticides, and fungicides. One of AMVAC's product lines is based on an active ingredient called "Technical Grade PCNB," which has been a FIFRA-registered pesticide product (EPA Registration No. 5481-197) since October 10, 1985. Plaintiff's Statement of

[5] OECA, FIFRA Enforcement Response Policy (Dec. 2009), at 7-8, available at http://cfpub.epa.gov/compliance/resources/policies/civil/erp/. None of the five situations where OECA "should issue a SSURO" appear to apply to AMVAC's PCNB products, and neither of the two situations where OECA "may issue a SSURO" would apply unless EPA has determined that AMVAC's PCNB products involve "serious violations that present a threat of harm." There is nothing in the record that demonstrates that EPA made such a determination before issuing the SSURO.

Uncontested Material Facts ("Stmt.") at ¶ 1.[6] It is the Technical Grade PCNB approved under this Registration that is at issue here. Stmt. at ¶ 1.[7]

PCNB products are primarily used in non-crop applications to prevent "snow mold" fungus growth on golf course fairways and greens. These products are only effective for this purpose if applied in late October and November. Stmt. at ¶ 2. When applied correctly, they prevent potentially significant damage and destruction of turf, and thus help users avoid the need to use more and different fertilizers, herbicides, and pesticides to repair and replace the turf. Stmt. at ¶ 2.

In 1993, AMVAC detected trace quantities of Impurity X in its Technical Grade PCNB products. On July 2, 1993, AMVAC notified EPA about these trace quantities of Impurity X pursuant to 7 U.S.C. § 136d(a)(2). Stmt. at ¶ 3. The amounts detected were far below the level (> 0.1 percent by weight) that automatically requires inclusion in the CSF under 40 C.F.R. § 158.320(d). Stmt. at ¶ 3. EPA reviewed the submission on July 23, 1993, and determined that:

> HED staff indicated that [Impurity X], as reported in this submission, are a *known PCNB contaminant. ... A routine non-expedited review* has been recommended.

Stmt. at ¶ 4 (emphasis added).[8]

On two occasions following the submittal of its July 2, 1993 letter to EPA, AMVAC submitted to EPA applications for amended registration to amend the CSF for Technical Grade

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[6] References herein and in AMVAC's Statement of Uncontested Material Facts to the Appendix, or "App.," are to the Appendix submitted by AMVAC in support of its motion for summary judgment. References to the Administrative Record, or "AR," are to the administrative record for the SSURO as certified to the Court by EPA.

[7] PCNB is pentachloronitrobenzene or "PCNB." Stmt. at ¶ 1. In addition, each of the end-use pesticide products that are formulated from Technical Grade PCNB is separately registered. Distribution and sale of these products is also prohibited by the SSURO.

[8] EPA did not make this review available to Plaintiff or the Court until after the TRO proceeding.

PCNB, as EPA regulations require. First, on December 4, 1998, AMVAC submitted an amended CSF to slightly change the concentration of the active ingredient in Technical Grade PCNB products. Stmt. at ¶ 5. EPA approved the amended CSF on December 29, 1999. Stmt. at ¶ 5. On January 10, 2005, AMVAC prepared a second CSF amendment to submit to EPA, reflecting that AMVAC would be a supplier of Technical Grade PCNB. Stmt. at ¶ 6. The amendment did not change any of the listed chemicals or percent weights of individual ingredients. Stmt. at ¶ 6. EPA approved this second CSF by letter dated April 21, 2005. Stmt. at ¶ 6. On both occasions EPA approved the CSF without requiring that Impurity X be identified even though it specifically knew since 1993 that this impurity was a known contaminant in PCNB. Stmt. at ¶¶ 5-6.

In addition to the 1998 and 2005 CSF submissions, in 2003 AMVAC applied to amend its Technical PCNB registration to make label changes unrelated to the current controversy. Stmt. at ¶ 7. On December 11, 2003, EPA approved the revised label. Stmt. at ¶ 7. Again, EPA did not require that Impurity X be identified on the CSF.

In July 2006 EPA issued a Reregistration Eligibility Decision ("RED") for PCNB.[9] As part of that process EPA was required to make a new determination that the product "meets the requirements of [FIFRA Section 3(c)(5)]." 7 U.S.C. § 136a-1(g)(2)(C). EPA, while addressing other contaminants in PCNB, did not raise any concerns regarding the presence of Impurity X in PCNB nor did it require any additional testing regarding Impurity X. Stmt. at ¶ 8.

In December 2009, discussions began between EPA and AMVAC regarding the presence of Impurity X in Technical Grade PCNB based on a new study done by Australian authorities. On December 16, 2009, AMVAC provided samples of its Technical Grade PCNB to EPA. Stmt. at ¶ 9. Those samples were sent by EPA for analysis in January of 2010, and were separately

[9] Available at http://www.epa.gov/oppsrrd1/REDs/pcnb_red.pdf.

analyzed on AMVAC's behalf by an independent laboratory. Stmt. at ¶ 9. All results were sent to EPA in March of 2010, along with other materials. Stmt. at ¶ 9. As in 1993, the data submitted by AMVAC showed that Impurity X was present in trace amounts. Stmt. at ¶ 9.

A teleconference between AMVAC and EPA officials was held in March of 2010. Stmt. at ¶ 10. The call focused on the PCNB manufacturing process, including where in that process Impurity X may have been generated. Stmt. at ¶ 10. Prior to the call, EPA reviewed AMVAC's 1993 6(a)(2) submission that disclosed the presence of the impurity. Stmt. at ¶ 10. EPA never indicated that the CSF for AMVAC's Technical Grade PCNB product needed to be amended or that the agency was considering issuing a SSURO for this product. Stmt. at ¶ 10.

At AMVAC's request, a follow-up meeting with EPA was held on June 3, 2010. Again, EPA was informed that trace amounts of Impurity X are unintentionally formed in the manufacture of PCNB. Stmt. at ¶ 11. The Agency was again reminded of AMVAC's 1993 submission. Stmt. at ¶ 11. EPA never stated that AMVAC's CSF was in violation of FIFRA, or that the agency was considering issuing a SSURO to stop all sales of products under the Registration. Stmt. at ¶ 11.

Between June 3, 2010 and the issuance of the SSURO on August 12, 2010, EPA did not contact AMVAC regarding whether Impurity X should be identified on the CSF. On August 12, 2010, without prior notice to AMVAC and without any opportunity to be heard, EPA issued a SSURO, stating in pertinent part:

> The Respondents are hereby ordered to **immediately** cease the distribution, sale, or use of Technical Grade PCNB 95% (EPA Reg. No. 5481-197) and any PCNB-containing pesticide products derived from the technical grade pesticide or from the same source of PCNB active ingredient (collectively, the "violative pesticide products") which are in the ownership, control, or custody of the Respondents, wherever the violative pesticide products are located.

See Stmt. at ¶ 12 (emphasis in original). The SSURO required AMVAC to immediately cease all sales and distribution of its registered Technical Grade PCNB product, *regardless* of whether that product contained any amount of Impurity X. Stmt. at ¶ 12.

The product AMVAC registered and sold does not differ from that which is the subject of the SSURO. Stmt. at ¶ 13.

The SSURO does not allege that EPA determined that the amount of Impurity X present in Technical Grade PCNB is "toxicologically significant," as set forth in 40 C.F.R. § 158.320(c). Rather, the SSURO alleges that Impurity X is generally a "substance or class of substances known to be of toxicological significance." Stmt. at ¶ 14. The SSURO also alleges that AMVAC's formula for its Technical Grade PCNB product differs from that submitted by AMVAC to EPA in the CSFs solely because it did not identify Impurity X. Stmt. at ¶ 14. Based on this premise alone, EPA claimed that AMVAC's sales of PCNB products violated Section 12(a)(1)(C) of FIFRA. EPA does not dispute that Impurity X was present in Technical Grade PCNB when all prior approvals were issued. The SSURO does not allege that the failure to identify this impurity constitutes an imminent or other threat to human health or the environment.

Prior to issuing the SSURO, EPA provided no notice to AMVAC: (1) that it had determined Impurity X to be a "toxicologically significant" impurity within the meaning of 40 C.F.R. § 158.320(c); (2) that the agency believed the presence of Impurity X required an amended CSF for Technical Grade PCNB products; or (3) that it believed AMVAC was violating FIFRA. The agency did not disclose the basis for its apparent decision (reflected in its TRO opposition filings but not in the SSURO) that the CSF should have identified Impurity X based on a few sentences in the 1988 preamble to a new FIFRA rulemaking, nor did it share

whatever data it planned to rely on to support the allegations in the SSURO.[10] The SSURO, moreover, provides no basis for the statement that Impurity X is a "substance or class of substances known to be of toxicological significance." At no time during the prior reviews and approvals of the CSF did EPA determine that these trace amounts of Impurity X associated with the active ingredient were "toxicologically significant" so as to require inclusion in the CSF under 40 C.F.R. § 158.320(c).[11]

Application of AMVAC's PCNB products typically must occur between October and November and about 80% of all its sales of the product take place in August, September and October each year. Stmt. at ¶ 16. At least one state (New Mexico) has, based solely on this SSURO, cancelled its state-issued registration for Technical Grade PCNB. Stmt. at ¶ 14. EPA also posted a webpage regarding the SSURO and containing the agency's incorrect and unsupported claims.[12] As a result of this, AMVAC is currently losing more than $20 million in annual business that cannot be recovered.

III. ARGUMENT

The SSURO expressly prohibits AMVAC from selling all of its registered Technical Grade PCNB product identified by the Registration. EPA's SSURO, therefore, revoked AMVAC's Registration for its PCNB product, and did so without providing any pre-deprivation notice and/or opportunity to be heard. It is undisputed that the Registration has always approved the sale of AMVAC's Technical Grade PCNB product with Impurity X, and EPA has never

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[10] The 1988 preamble language relied upon after the fact by EPA in its TRO papers is discussed in Section III.G.3. below.

[11] The current regulation requires listing of this type of impurity in a CSF *only* if there is a determination of "toxicological significance," 40 C.F.R. § 158.320(c). This regulation was amended in 2007 to make it clear that only EPA could make this determination. *See* 72 Fed. Reg. 60934, 60971 (Oct. 26, 2007).

[12] http://www.epa.gov/compliance/resources/cases/civil/fifra/americanvanguard.html

required that Impurity X be listed on the CSF. By revoking the Registration without any prior notice, EPA has violated the statutory protections of FIFRA, Section 558 of the Administrative Procedure Act, 5 U.S.C. § 558, and AMVAC's Fifth Amendment due process rights.

Assuming *arguendo* that the SSURO has not revoked the Registration without prior notice and an opportunity to be heard, it is nonetheless arbitrary, capricious and inconsistent with law. First, the SSURO is arbitrary as a matter of law because there is no contemporaneous record to support the SSURO and, without such a record, the order may not stand. Second, the decision is irrational because it amounts to a claim by EPA that AMVAC violated FIFRA by selling the same product that EPA specifically approved. Third, the SSURO is premised solely upon AMVAC's alleged failure to identify Impurity X on the CSF, but the record contains no determination by EPA that Impurity X is toxicologically significant. That determination is necessary to trigger the requirement for AMVAC to identify Impurity X.

A. The SSURO Violates FIFRA Because It Revokes the Registration Without Following the Protections Afforded AMVAC by FIFRA Section 6.

The SSURO expressly prohibits AMVAC's sale of any of its registered Technical Grade PCNB products under the Registration, *regardless* of whether that product contains Impurity X:

> The Respondents are hereby ordered to **immediately** cease the distribution, sale, or use of Technical Grade PCNB 95% (EPA Reg. No. 5481-197) and any PCNB-containing pesticide products derived from the technical grade pesticide or from the same source of PCNB active ingredient (collectively, the "violative pesticide products") which are in the ownership, control, or custody of the Respondents, wherever the violative pesticide products are located.

See App. at 73 (emphasis in original). Moreover, AMVAC makes only one "kind" of PCNB and Impurity X is a known contaminant created inadvertently in the manufacturing process. App. at 316. Issuing a SSURO that targets all uses of a particular FIFRA registration completely undermines any notion that the Registration, which is not being formally suspended or cancelled, remains valid:

> As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of [FIFRA].

7 U.S.C. § 136a(f)(2). Issuing this SSURO also ignores the procedural protections specifically set forth in FIFRA Section 6, which EPA is required to provide when the agency's goal is to suspend and/or cancel all use of a registration. If EPA now believes that it has a sufficient basis to decide that the current terms of the Registration need to be changed (*e.g.*, it now wants the CSF to list Impurity X because it has now determined that Impurity X is "toxicologically significant"), and does not want the product sold in the meantime, then it must follow the procedures specified by FIFRA Section 6.[13] FIFRA Sections 6(b) and 6(c) establish the mechanisms by which EPA can compel the registrant to make "necessary changes" if it declines to do so voluntarily. *See* 7 U.S.C. §§ 136d(b) (cancellation and change in classification) & (c) (suspension). This is clearly established by the legislative history to the FIFRA amendments that created the right to a cancellation hearing.

Prior to 1964, the sole mechanism by which the U.S. Department of Agriculture ("USDA") (the predecessor to EPA in registering pesticides) could remove a pesticide product from the market that it believed no longer satisfied the statutory standard for registration was to take enforcement action to demonstrate that the product was "misbranded." FIFRA §§ 2(u) & 3(a) (1947), 61 Stat. 165-166. Under the 1947 version of FIFRA, USDA was required to issue or continue a pesticide registration even if it did not agree that the product in question met the statutory standard for registration, but the registrant then had to bear the risks of enforcement action including imposition of penalties and seizure of the affected product in order to obtain any hearing on any purported deficiencies. FIFRA § 4(c) (1947), 61 Stat. 168.

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[13] EPA has admitted that the SSURO is intended to suspend all sales and use of PCNB under the Registration while it mulls over cancellation. App. at 309.

The 1964 FIFRA Amendments were enacted to replace this unsatisfactory mechanism with an administrative hearing concerning any decision to refuse or cancel a pesticide registration. H.R. Rep. No. 88-1125, *as reprinted in* 1964 U.S.C.C.A.N. 2166, at 2167. This Report states in pertinent part:

> The bill would correct this situation and afford greater protection to the public by repealing the authority for registration under protest. In its place the bill provides that applicants dissatisfied with the Secretary's action in refusing or canceling registration may have recourse to advisory committee proceedings, public hearings, and eventually judicial review. Thus the bill affords adequate protection to the public, and *protects applicants for registration from arbitrary or ill-advised action* by the Department.

Id. (emphasis added).

In explaining the rationale for these changes, it was noted that, in order for a manufacturer to appeal from a decision by the Secretary to register a product under protest, "he must take actions which subject him to penalties, the product to seizure, and the public to possible danger if the Secretary's determination should prove to be correct." 109 Cong. Rec. 20079 (1964). It was also observed that the 1964 bill "permits the applicant or registrant to file objections and request a public hearing" and "provides better procedures to protect the applicant or registrant from any arbitrary determination by the Secretary of Agriculture." *Id.* This Circuit has confirmed that the purpose of the 1964 Amendments to FIFRA was "to eliminate the system of protest registration, and substitute the present administrative mechanism for canceling registrations." *Envtl. Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 593 (D.C. Cir. 1971).

Allowing EPA to unilaterally issue a SSURO as a means of compelling changes in the registration for Technical PCNB rather than the formal adjudicatory procedure for cancellation or suspension of registrations contained in Section 6 completely undermines those requirements

legislated by Congress in 1964.[14] Registrants will once again be at risk of enforcement action whenever EPA decides that it wants to change its mind regarding the approval of any aspect of current registrations.[15]

B. The SSURO Effectively Revokes AMVAC's Validly-Issued Registration, Which Permits It to Distribute and Sell Its PCNB Product Containing Impurity X But Without Identifying Impurity X in the Confidential Statement of Formula.

As explained in Section II.A above, EPA makes specific determinations whenever it approves any pesticide registration application, including an application to amend a CSF. Thus, to grant AMVAC's applications to amend the CSF for its Technical Grade PCNB product, which EPA did in 1999 and again in 2005, EPA necessarily and *expressly* determined that the composition was correct, and that the product *as manufactured* was not in violation of any provision of FIFRA, including FIFRA Section 12(a)(1)(C). EPA knew that Impurity X was present in AMVAC's PCNB product, because AMVAC disclosed it in 1993, and EPA found that it was a known contaminant. App. at 112. Instead of making any affirmative determination of toxicological significance, EPA decided to relegate this issue to "a routine non-expedited review." *Id.*

The same fact that is before the agency now was before it in 1993, 1999 and 2005 — AMVAC's PCNB contains trace amounts of Impurity X. The same product containing

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[14] Pursuant to 7 U.S.C. § 136m, a party who suffers a loss with respect to a suspended registration is *entitled to indemnification from EPA.* There is no corresponding indemnification provision for a SSURO that causes a loss. A suspension order, unlike a SSURO, also requires the agency to assert the presence of an imminent hazard, and even in that context prior notice is required. 7 U.S.C. § 136d(c). *See* Section II.A.6, *supra*. Using the SSURO insulates the agency from its indemnification and eliminates the burden Congress imposed on it when suspension of a registration was the agency's goal.

[15] This is not the first challenge to EPA's new effort to use enforcement sanctions to evade the requirements of cancellation proceedings, even though it was cancellation that was at issue. *See Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131 (D.C. Cir. 2010), *on remand,* No. 09-CV-445 (D.D.C.); *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430 (D.C. Cir. 1986).

Impurity X has always been sold and was approved by EPA since 1993 without identifying it in the CSF. Under Section 3(f)(2), EPA cannot reasonably claim that there is a purported violation of FIFRA based on the same information that was before it when it made the determinations required by FIFRA Section 3(c)(5).

For at least two reasons, EPA cannot just ignore its prior determinations made under FIFRA Section 3(c)(5) that AMVAC's Technical Grade PCNB product satisfies all requirements of FIFRA. First, it is undisputed that the presence of Impurity X in AMVAC's PCNB product has been known to EPA since 1993, when AMVAC notified the agency. App. at 112. EPA reviewed the submission, noted the presence of Impurity X, and approved the CSF on three separate occasions without requiring that Impurity X be identified. App. at 115, 120. It must be presumed that EPA followed its established procedures in approving the CSFs, especially under these circumstances. *See, e.g.*, *VanderMolen v. Stetson*, 571 F.2d 617, 624 (D.C. Cir. 1977) ("It is, of course, a fundamental tenet of our legal system that the Government must follow its own regulations."). That means EPA made all necessary determinations, including that the CSF was correct as written.

Second, former 40 C.F.R. § 158.32(e), which was in effect when EPA approved the revised CSFs for Technical Grade PCNB in 1999 and 2005, provided that "[d]ata which previously have been submitted need not be resubmitted unless resubmission is specifically requested by the Agency."[16] Moreover, 40 C.F.R. § 159.152(c) clearly states that a submission under FIFRA Section 6(a)(2) satisfies the obligation that a registrant would otherwise have under 40 C.F.R. § 152.50(f)(3) to submit information covered by Section 6(a)(2) with an application

[16] This provision was promulgated in 1988 and was in effect when EPA approved the revised CSFs for Technical Grade PCNB in 1998 and 2005. *See* 53 Fed. Reg. 15952, 15991 (May 4, 1988). It was not retained when Part 158 was recodified in 2007. *See* 72 Fed. Reg. 60934, 60957 (Oct. 26, 2007).

for registration or amended registration, including an application to amend a CSF. This means that AMVAC was not obligated to resubmit the 1993 data. Further, there is nothing in the record to suggest that while EPA was considering the 1998 and 2005 CSFs, it requested that AMVAC submit additional data or resubmit the data regarding the presence of Impurity X in its Technical Grade PCNB previously submitted in 1993. Nor is there any suggestion that AMVAC had additional data that it failed to submit. EPA only requested additional information in early 2010 and AMVAC complied with that request immediately.

These considerations illustrate why Congress decided that it must be presumed that, absent a cancellation proceeding, a registered product is in compliance with registration requirements. 7 U.S.C. § 136a(f)(2). A registrant must have a reasonable degree of certainty that if it follows the registration process, as AMVAC did here, then it can invest in, manufacture and sell the approved product without fear that it will be suddenly and abruptly divested of that registration without prior notice or an opportunity to be heard and be deemed to have been in violation of FIFRA retroactively. The SSURO completely undermines that provision.

There is no allegation in the SSURO that AMVAC is selling an unregistered product. The product being sold is the same product that was described in the CSF that EPA reviewed and approved three times. If the Court were to accept EPA's claim that it can disregard its own validly issued registrations with no prior notice or opportunity to be heard, then no registrant under FIFRA could ever rely on an EPA registration to authorize the activities the registration purports to authorize. Nor could any user rely on the legitimacy of a registration to authorize use of the product. EPA could summarily halt all distribution, sales, or use of a registered product at any time, and find a registrant to be retroactively in violation of FIFRA if the agency decides to change its mind about what it wants reported in the CSF.

C. By Effectively Revoking AMVAC's Registration Without Any Prior Notice or Opportunity to Demonstrate or Achieve Compliance, EPA Has Violated Section 558 of the Administrative Procedure Act.

Even if EPA was permitted to use a SSURO to suspend all sales under a FIFRA registration, notwithstanding FIFRA Section 6, it must still give prior notice and opportunity to respond because the SSURO, when used in that manner, effectively revokes a license. Section 558 of the APA provides in relevant part:

> Except in cases of willfulness or those in which public health, interest, or safety requires otherwise, the withdrawal, suspension, revocation, or annulment of a license is lawful only if, before the institution of agency proceedings therefore, the licensee has been given —
>
> (1) notice by the agency in writing of the facts or conduct which may warrant the action; and
>
> (2) opportunity to demonstrate or achieve compliance with all lawful requirements.

5 U.S.C. § 558(c).

For purposes of the APA, "license" is defined broadly to include "the whole or part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission." 5 U.S.C. § 551(8). AMVAC's registration for its Technical Grade PCNB is a "license" as defined by the APA. *See Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010), *on remand*, No. 09-CV-445 (D.D.C.); ("A FIFRA registration is a product-specific *license* describing the terms and conditions under which the product can be legally distributed, sold, and used," citing 7 U.S.C. § 136a(a), (c)-(e)) (emphasis added); *Washington Toxics Coal. v. EPA*, No. CO1-132C, 2002 U.S. Dist. LEXIS 27654, *25 (W.D. Wash. July 2, 2002) ("EPA describes a registration as 'a license which establishes the terms and

conditions under which the pesticide product may be lawfully sold, distributed, or used.'"); *see also Air North America v. Dep't of Transp.*, 937 F.2d 1427, 1436-38 (9th Cir. 1991).[17]

The SSURO expressly prohibits AMVAC's sale of any of its *registered* Technical Grade PCNB (EPA Reg. No. 5481-197). It thus effectively revokes AMVAC's license. *See* Section III.A. *supra*. Unless one of the exceptions in Section 558(c) applies in this case, which EPA has not alleged, AMVAC was entitled to written notice by EPA and an opportunity to demonstrate or achieve compliance with lawful requirements, prior to the institution of proceedings to revoke its license for its registered PCNB product, and certainly prior to an order that summarily and immediately revoked the license. It is undisputed that AMVAC was afforded none of the procedural protections afforded by Section 558(c).

Section 558(c) "is designed to preclude the withdrawal of licenses, except in cases of willfulness or the stated cases of urgency, without affording the licensee an opportunity for the correction of conduct questioned by the agency." Administrative Procedure Act: Legislative History, S. Doc. No. 248, 79th Cong., 2d Sess. 35 (1946). Its purpose is to provide a licensee threatened with the termination of its license an opportunity to correct its transgressions *before* actual suspension or revocation of its license resulted. *See The Blackwell College of Business v. Attorney General*, 454 F.2d 928, 933-34 (D.C. Cir. 1971). *Accord Gallagher & Ascher Co. v. Simon*, 687 F.2d 1067, 1074 (7th Cir. 1982); *Atlantic Richfield Co. v. United States*, 774 F.2d 1193, 1200-1201 (D.C. Cir. 1985); 1947 Attorney General's Manual on the Administrative Procedure Act at 90-91.

There has been no finding by EPA that AMVAC willfully violated the terms of the Registration, nor has EPA made any finding that "public health, interest, or safety" exempted the

[17] EPA is an "agency" as defined by the APA. *See* 5 U.S.C. § 551(l).

SSURO from the provisions of Section 558(c) requiring pre-deprivation notice and opportunity to correct. Because none of the exceptions to Section 558(c) were invoked, EPA was required by Section 558(c) to give AMVAC notice in writing of the facts or conduct that may have warranted the revocation of its licenses and an opportunity to demonstrate or achieve compliance with all lawful requirements. Instead, with the SSURO effectively terminating AMVAC's license for its registered PCNB product by suspending all uses under it, EPA instituted proceedings against AMVAC without any prior written notice and without any opportunity to demonstrate compliance.

Given the foregoing, the SSURO must be set aside because EPA failed to give AMVAC the notice and opportunity to demonstrate or achieve compliance required by 5 U.S.C. § 558(c). *See, e.g.*, *Anchustegui v. Dep't of Agric.*, 257 F.3d 1124, 1129 (9th Cir. 2001) (agency's cancellation of grazing permit reversed when agency failed to provide the permittee with an opportunity to achieve compliance or to demonstrate that compliance had been achieved before the agency instituted the proceeding to cancel the permit); *Blackwell*, 454 F.2d at 933-936 (approved status of school for attendance by nonimmigrant aliens constituted license; notice and hearing under Section 558(c) necessary prior to revocation of status); *Capital Produce Co., Inc. v. United States*, 930 F.2d 1077, 1079, 1081 (4th Cir. 1991) (holding that failure to provide prior written warning that conduct was deficient and an opportunity to correct deficiencies required that license suspension must be set aside); *The Pillsbury Co. v. United States*, 18 F. Supp. 2d 1034 (Ct. Int'l Trade 1998) (Customs Service violated 558(c) in revoking plaintiff's license to use Exporter's Summary Procedure and blanket waiver; obligation established by APA

required Customs to notify the exporter of the reason for revoking license and to provide exporter with opportunity to address that reason).[18]

D. EPA Violated AMVAC's Fifth Amendment Due Process Rights by Revoking the Registration Without Prior Notice and an Opportunity to Be Heard.

Even if EPA has the discretion to choose an enforcement mechanism that avoids the procedural protections provided by FIFRA and the APA, it cannot ignore constitutional due process protections afforded to AMVAC when that weapon takes a constitutionally-protected property interest.

"The essence of due process is the requirement that 'a person in jeopardy of serious loss [be given] notice of the case against him and opportunity to meet it.'" *Mathews v. Eldridge*, 424 U.S. 319, 348 (1976) (quoting *Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U.S. 123, 171-172 (1951) (Frankfurter, J., concurring)). The Supreme Court has established that "before a person is deprived of a protected interest, he must be afforded opportunity for some kind of a hearing, 'except for extraordinary situations where some valid governmental interest is at stake that justifies postponing the hearing until after the event.'" *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 570 n.7 (1972) (quoting *Boddie v. Connecticut*, 401 U.S. 371, 379 (1971)). Even where the government's interests justify immediate action, a full hearing must be available

[18] EPA previously has been stopped by this Court for failing to afford notice and an opportunity to be heard before the agency effectively revoked AMVAC's license via the SSURO. Chief Judge Lamberth issued a temporary restraining order to prevent enforcement of a SSURO in *Biolab, Inc. v. EPA*, No. 1:98CV01113 (D.D.C. May 6, 1998). App. at 303-04. In that case, the company had an unregistered product that was never previously reviewed or approved by EPA for use under FIFRA. EPA issued a SSURO to Biolab ordering the company to stop selling two products that were used for "shock treatment" of swimming pools, claiming that the products had *never been registered under FIFRA*. App. at 256. The SSURO was issued to Biolab just as the company's brief selling season for the product was about to commence. App. at 272-73. Unlike in AMVAC's case, however, EPA engaged Biolab in an exchange of correspondence on the issue and, subsequently, formally afforded Biolab an opportunity to show cause why a SSURO should not be issued before issuing the order. App. at 247. No such protections were afforded AMVAC for its product, which was registered.

promptly after the temporary deprivation occurs. *See Goldberg v. Kelly*, 397 U.S. 254, 266-267 (1970). "To be meaningful, an opportunity for a full hearing and determination must be afforded at least at a time when the potentially irreparable and substantial harm caused by a suspension can still be avoided — *i.e.*, either before or immediately after suspension." *Barry v. Barchi*, 443 U.S. 55, 74 (1979) (Brennan, J., concurring in part).

The determination of what process is due before a deprivation of a right occurs, including whether a post-deprivation hearing is adequate, requires consideration of the now-familiar *Mathews v. Eldridge* factors: (1) the nature of the private interest affected by the government's action; (2) the government's interest, including the fiscal and administrative burdens that would be placed on it by additional procedures; and (3) the risk of erroneous deprivation of the private interest through the procedure used and the value of additional safeguards. *See Eldridge*, 424 U.S. at 335.

1. AMVAC's Registration is a Constitutionally-protected property interest.

As the holder of a government-issued license for its registered Technical Grade PCNB product, AMVAC has a property right to produce and market that product. *See, e.g.*, *Barchi*, 443 U.S. at 55 (suspension of horse trainer's license without pre-deprivation hearing unconstitutional because neither rule nor practice applied to trainer assured timely post-deprivation hearing); *Indus. Safety Equip. Ass'n, Inc. v. EPA*, 837 F.2d 1115, 1122 (D.C. Cir. 1988) ("There is no question that appellants possess cognizable property interests in their respirator certifications."); *Richardson v. Town of Eastover*, 922 F.2d 1152, 1156 (4th Cir. 1991) (license issued by state which can be suspended or revoked only upon a showing of cause creates a property interest protected by the Fourteenth Amendment). This property right is protected by the Due Process Clause of the Fifth Amendment to the United States Constitution, which guarantees that it cannot

be modified, suspended, revoked or withdrawn without the opportunity to be heard at a meaningful time and in a meaningful manner. *See, e.g., Eldridge*, 424 U.S. at 348; *Bell v. Burson*, 402 U.S. 535 (1971).

AMVAC's PCNB is largely sold in August through October for use in October and November. Stmt. at ¶ 16. Once those sales are lost, they cannot be recovered. AMVAC is in the process of losing over $20 million in sales of its PCNB product. App. at 323. AMVAC's Registration is a valuable asset to AMVAC and its employees for their economic well-being and reputational interests. AMVAC, moreover, cannot be made whole for its loss of this year's sales if the effective revocation of its Registration is later vacated. *See Dixon v. Love*, 431 U.S. 105, 113 (1977). EPA has sovereign immunity from any action by AMVAC seeking to recover its losses resulting from a vacated SSURO and, additionally, the agency, by issuing the SSURO, has side-stepped the FIFRA process that might have afforded AMVAC some level of indemnification. *See* 7 U.S.C. § 136m; *see also* n.13, *supra*.[19]

2. EPA alleges no danger or harm to justify ignoring pre-deprivation constitutional protections.

EPA has not alleged that the facts upon which the SSURO are based present any sort of safety, health or environmental danger or hazard. App. at 70-73. The presence of Impurity X in Technical Grade PCNB has been specifically known to the agency since 1993. EPA, on at least three occasions subsequent to AMVAC's 1993 disclosure, determined that the registration complied with FIFRA in all respects. EPA has had ample opportunity prior to issuing the SSURO to afford AMVAC proper notice and opportunity to comment, with minimal fiscal or

[19] Here, the private interest affected by EPA's decision to issue the SSURO is AMVAC's license for its Technical Grade PCNB product. Unlike the social security recipients in *Eldridge* who could be made whole by retroactive payments if their claims were sustained in a post-deprivation hearing, there may be circumstances where "a licensee is not made entirely whole if his suspension or revocation is later vacated." *Dixon*, 431 U.S. at 113. That is the case here.

administrative burdens. The fact that EPA might now be changing its mind about identifying the impurity on the CSF is insufficient. FIFRA Section 6 itself provides risk-based standards in connection with suspension or cancellation of a registration, and even then a pre-deprivation hearing is required. *See* 7 U.S.C. §§ 136d(b), (c).

3. There is a substantial risk of erroneous deprivation because of the demonstrable legal and factual defects upon with the SSURO is based.

If AMVAC's PCNB complies in all respects with the current approved CSF, there is *no* violation of FIFRA and AMVAC is, and has been, erroneously deprived of its property. Unlike the situation in *Dixon v. Love*, where the state suspended motor vehicle licenses based on "largely automatic" criteria, 431 U.S. at 113, there is nothing automatic about the criteria being applied here. As explained in Sections III.E-F, below: (1) there is no contemporaneous record provided upon which the SSURO can be based and, as a matter of law, it is therefore invalid; and (2) what record does exist demonstrates that EPA (a) never made a determination of toxicological significance that is a necessary prerequisite before the alleged violation can be found; (b) relied, after-the-fact, on an invalidly promulgated legislative rule to support what it claims is the prerequisite determination of toxicological significance; (c) failed to consider, or disregarded, evidence of its prior conclusion that Impurity X in this context is not toxicologically significant; and (d) failed to explain the basis for the agency's change of position regarding whether Impurity X must be listed on the CSF.

E. As a Matter of Law, the Court Should Vacate the Order and Remand to the Agency Because EPA Has Failed to Offer a Contemporaneous Administrative Record for the SSURO.

1. Judicial review of the SSURO must be based on a proper contemporaneous record.

The substantive issue here is whether AMVAC violated FIFRA by not identifying Impurity X on the CSF for the Registration. That requirement only exists if EPA first determines

that Impurity X is "toxicologically significant" within the meaning of 40 C.F.R. § 158.320(c). Thus, the agency must demonstrate, based on a proper administrative record, that it made this determination and that such determination is not arbitrary, capricious or inconsistent with law. The Court need not reach this issue, however, because the "certified" record offered by EPA for the SSURO is, on its face, deficient and precludes effective judicial review by this Court. The Court should, therefore, vacate the SSURO and remand the matter to the agency. *American Petroleum Institute v. Johnson*, 541 F. Supp. 2d 165, 185 (D.D.C. 2008) (Friedman, J.).

Judicial review of an agency final action under the APA must be based on review of the administrative record that was before the agency at the time of its decision. 5 U.S.C. § 706; *Community for Creative Non-Violence v. Lujan*, 908 F.2d 992, 998 (D.C. Cir. 1990); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971). The court's review must "be based on the full administrative record that was before the [agency] at the time [it] made [its] decision." *Am. Bioscience v. Thompson*, 243 F.3d 579, 582 (D.C. Cir. 2001). In other words, to ensure fair review of an agency action, the court "should have before it neither more nor less information than did the agency when it made its decision." *Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("To review less than the full administrative record might allow a party to withhold evidence unfavorable to its case, and so the APA requires review of 'the whole record.' To review more than the information before the [agency] at the time [of its] decision risks our requiring administrators to be prescient or allowing them to take advantage of post hoc rationalizations.") (citations omitted); *American Petroleum Institute*, 541 F. Supp. 2d at 185 (agency may not rely on *post hoc* rationalizations provided by counsel); *Fund for Animals v. Williams*, 391 F. Supp. 2d 191, 196 (D.D.C. 2005) (citing *IMS v. Alvarez*, 129 F.3d 618, 623 (D.C. Cir. 1997));

In order to ensure that the administrative record contains "neither more nor less" information than was before the agency, "courts in this circuit have directed agencies to collect those materials that *were compiled by the agency that were before the agency at the time the decision was made*." *Fund for Animals*, 391 F. Supp. 2d at 196 (citing *James Madison Ltd v. Ludwig*, 82 F.3d 1085, 1095 (D.C. Cir. 1996)) (emphasis added). The on-the-record rule presupposes that some record exists *contemporaneously* with the challenged agency decision. *See, e.g., Camp v. Pitts*, 411 U.S. 138, 142 (1973) (review limited to "administrative record *already in existence*, not some new record made initially in the reviewing court") (emphasis added); *Southwest Center for Biological Diversity v. United States Forest Service*, 100 F.3d 1443, 1450 (9th Cir. 1996) (review "typically focuses on the administrative record *in existence at the time of the decision* and does not encompass any part of the record that is made initially in the reviewing court") (emphasis added); *Envtl. Defense Fund, Inc. v. Costle*, 657 F.2d 275, 284 (D.C. Cir. 1981) ("review of agency action is normally confined to the full administrative record before the agency *at the time the decision was made*") (emphasis added).

2. EPA's "certified" record is defective as a matter of law because it was not made contemporaneously with the SSURO.

The SSURO is a specific adjudication of whether AMVAC has violated FIFRA because it failed to identify Impurity X on the CSF for the Registration. In rendering that adjudication, "the Director"[20] was obligated to make certain findings of fact and to reach certain conclusions

[20] The SSURO alleges that it was issued pursuant to a delegation of authority from the "EPA Administrator to the Director of the Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, EPA." App. at 70. The delegation of authority to issue SSUROs provided by EPA to AMVAC's counsel, but not included in the agency's certified record, is from an EPA "*Assistant* Administrator" to the "Director, *Toxics and Pesticides Enforcement Division*, Office of Enforcement and Compliance Assurance." App. at 132 (emphasis added). Accordingly, absent evidence that the Director of the Waste and Chemical Enforcement Division has properly delegated authority to issue the SSURO, it is without legal authority and invalid. *See Flav-O-Rich, Inc. v. NLRB*, 531 F.2d 358,

of law. But the "record" here as presented in EPA's "Certified Index" is so confused and unclear that it cannot be determined what was or should have been in it. There is no indication that the Director made the required contemporaneous "record" of the materials that were considered by her when she made the findings and issued the SSURO. To the contrary, the unsworn certification submitted by EPA to the Court states that two EPA officials claiming to be custodians of the "administrative record" asked other unknown EPA employees, sometime *after* the SSURO was issued, to compile what the Director now believes *might* have been the record for the SSURO at the time it was issued. App. at 1. That is not a contemporaneous record. There is nothing to indicate what was actually before her when she issued the SSURO.

By way of further illustration, the entire last section of what EPA asserts in its index is part of the record is labeled "Documents Filed with EPA's Opposition to AMVAC's Petition for TRO (including referenced attachments)." App. at 5. Every one of those documents was prepared after the SSURO was issued, and in connection with litigation; they could not possibly have been contemporaneously compiled or considered by the Director prior to issuing the SSURO on August 12, 2010. *See Overton Park*, 401 U.S. at 419 (criticizing lower court's reliance on "post hoc" litigation affidavits in reviewing agency action); *Nat'l Coal. Against the Misuse of Pesticides v. Thomas*, 809 F.2d 875, 882-83 (D.C. Cir. 1987) (rejecting *post hoc* rationalizations of counsel advanced to remedy inadequacies in the agency's record); *Am. Petroleum Inst.*, 541 F. Supp. 2d at 185; *Ad hoc Metals Coalition v. Whitman*, 227 F. Supp. 2d 134, 137 (D.D.C. 2002) (Friedman, J.).

363-64 (6th Cir. 1976) ("It is a fundamental rule of administrative law that '[t]he one who decides [a case] must hear [it].' *United States v. Morgan*, 298 U.S. 468, 481, (1936). *A necessary corollary of this principle is that he who decides the case must have authority to do so*.") (emphasis added).

The Supreme Court has held that where the "failure to explain administrative action … frustrated effective judicial review, the remedy was … to obtain from the agency … such additional explanation of the reasons for the agency decision as may prove necessary." *Camp*, 411 U.S. at 142-43. Thus, "the proper course in a case with an inadequate record is to vacate the agency's decision and to remand the matter to the agency for further proceedings." *Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 347 (D.C. Cir. 1989); *see Camp*, 411 U.S. at 143; *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

This defect cannot be cured in this proceeding. EPA's decision to issue the SSURO was made in a process that did not provide AMVAC with notice or an opportunity to be heard, to offer competing evidence or legal argument, or to otherwise participate in any proceedings before the agency. This adjudication was conducted in secret and resulted in an "order" that did not allow anyone other than the proponent of the order — EPA — to submit evidence, comment or argument.[21] It is virtually unprecedented for an agency to complete an adjudication and issue an order shutting down a licensed business, absent the threat of imminent harm, without providing potentially affected persons with adequate notice and opportunity to be heard. It is, likewise, virtually unprecedented for an agency to complete such a closed adjudication and then argue that a reviewing court is limited to considering only the one-sided "record" that is the inevitable result of such a closed proceeding. Consequently, any contemporaneous "administrative record" offered to the Court in response to AMVAC's motion, to the extent one even exists for the SSURO, cannot, as a matter of law, withstand the "thorough, probing, in-depth review" the APA requires and should be rejected by the Court. *See Overton Park*, 401 U.S.

[21] The single March 2010 phone call and June 2010 meeting between AMVAC and EPA did not discuss the agency's determination of toxicological significance with respect to Impurity X in this context.

at 415; *see also Louisiana Ass'n of Indep. Producers & Royalty Owners v. FERC*, 958 F.2d 1101, 1115 (D.C. Cir. 1992) ("A corollary to the rule that the whole record be considered is that interested parties must have an opportunity to introduce adverse evidence and criticize evidence introduced by others.").

F. Even If the So-Called "Record" Offered by EPA Is Not Defective as a Matter of Law, It Is Both Over-Inclusive and Under-Inclusive.

Should the Court consider the purported "record" submitted by EPA not to be defective because it was not contemporaneously created, certain materials must be excluded as inappropriate while others must be included as they were improperly ignored.[22]

The record provided by EPA is over-inclusive. There is a facsimile dated July 1, 2010 that appears to be sending information to someone in the office who might work for the Director. App. at 75-76. That facsimile claims to be 13 pages long, but nothing in the materials provided by EPA to the Court demonstrate what documents comprised the 13-page facsimile. The documents provided by EPA to the Court as the alleged "certified" record contain hundreds of pages of material, far more than the 13 referred to in the facsimile. Based on the facsimile at least, these hundreds of pages could not have been provided to or considered by the EPA Director who issued the SSURO, nor were they made available to AMVAC. *See Heckler*, 749 F.2d at 792 (remanding to agency record that was both over- and under-inclusive).

Second, the materials listed in the Index provided by EPA are demonstrably over-inclusive because they improperly include four declarations from EPA employees executed

[22] Should the Court find that EPA improperly disregarded certain information, the Court need not reach the merits, and the SSURO should be vacated and the matter remanded for proper consideration of this material by EPA. *See, e.g., Jack Wood Const. Co. v. U.S. Dep't of Transp.*, 12 F. Supp. 2d 25, 30 (D.D.C. 1998) (Friedman, J.) (agency decision arbitrary and capricious because it failed to consider relevant factors); *Carlton v. Babbitt*, 26 F. Supp. 2d 102, 108-09 (D.D.C. 1998) (Friedman, J.) (same).

weeks after the SSURO was issued. Those declarations were submitted by EPA in opposition to AMVAC's motion for a temporary restraining order. In fact, two of the four declarants, Herndon and Clark, were not involved at all with the subject matter of the SSURO prior to its issuance. As a matter of law, they could not be records created contemporaneously with the SSURO decision nor could they have been considered by the Director. *See Camp*, 411 U.S. at 142; *Overton Park*, 401 U.S. at 419; *Costle*, 657 F.2d at 284; *Fund for Animals*, 391 F. Supp. 2d at 196; *Am. Petroleum Inst.*, 541 F. Supp. 2d at 185; *Ad hoc Metals Coalition*, 227 F. Supp. 2d at 137. Therefore, none may be submitted to the Court as part of EPA's record for the SSURO.

The extra-record, after-the-fact declarations submitted by EPA go to one of the central substantive issues - whether EPA made the requisite determination of toxicological significance that would require that Impurity X be identified on the CSF - and directly to the propriety of EPA's action in issuing the SSURO. The declarations are classic *post hoc* rationalizations for the agency's action. EPA cannot support its action with an artificial record compiled after-the-fact and specially created for purposes of helping secure a favorable outcome upon judicial review. *See Heckler*, 749 F.2d at 792; *Consumer Fed'n of America and Public Citizen v. U.S. Dep't of Health and Human Services*, 83 F.3d 1497, 1507 (D.C. Cir. 1996) (rejecting extra-record declarations by the agency that went beyond simply illuminating reasons obscured but implicit in the administrative record); *Ad hoc Metals Coalition*, 227 F. Supp. 2d at 137 (*post hoc* rationalizations may not be relied upon to support agency decision).

EPA's certified record is under-inclusive as well.[23] EPA excluded the record of its initial review of AMVAC's 1993 voluntary disclosure of the presence of Impurity X in its PCNB product in which it acknowledged that Impurity X was a known contaminant and said it only

[23] An agency's obligation to supplement an under-inclusive record is well-established. *Ad hoc Metals Coalition*, 227 F. Supp. 2d at 140; *Carlton*, 26 F. Supp. 2d at 106-107 (D.D.C. 1998).

merited "a routine non-expedited" review. App. at 112. This information was in the agency's files and is clearly relevant to whether there was a violation of FIFRA at all. It must be included in the record, or the decision is necessarily arbitrary and capricious and must be vacated. *See Ad hoc Metals Coalition v. Whitman*, 227 F. Supp. 2d at 134, 140 (D.D.C. 2002) (Friedman, J.); *Kent County v. EPA*, 963 F.2d 391, 395-96 (D.C. Cir. 1992) (arbitrary and capricious for agency to fail to consider information in regional file).

G. The "Record" Certified by EPA Demonstrates That the SSURO Is Arbitrary, Capricious and Not in Accordance With Law.

To the extent the court considers the "record" offered by EPA, the SSURO is nonetheless arbitrary, capricious and inconsistent with law. It contains no necessary "determin[ation]" that Impurity X was "toxicologically significant" prior to issuing the SSURO. EPA did not consider AMVAC's 1993 6(a)(2) submission disclosing the presence of Impurity X in Technical Grade PCNB, EPA's own document that the presence of Impurity X triggered a mere recommendation for a non-expedited routine review, and EPA's subsequent approval of the CSFs for AMVAC's PCNB product on two separate occasions with the impurity information in hand. EPA fails to explain why it either ignored or reversed its prior view of Impurity X. The record is further defective to the extent it relies on what EPA now treats as a binding determination of toxicological significance made in a brief reference in a preamble to a 1988 rule, which was not promulgated as a legislative rule as required by law.

1. Standard of review.

A court, under § 706(2)(A), must carefully "review the record to ascertain that the agency has made a reasoned decision based on 'reasonable extrapolations from some reliable evidence,'" *Natural Res. Defense Council v. EPA*, 902 F.2d 962, 968 (D.C. Cir. 1990), to ensure that the agency has examined "the relevant data and articulate[d] a satisfactory explanation for its

action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). In *State Farm*, the Supreme Court offered several examples of circumstances in which an agency action would be considered arbitrary and capricious: situations where "the agency has relied on factors which Congress has not intended it to consider, *entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency*, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43 (emphasis added).

An agency may not rely upon mere conclusory statements to explain its decision. *See, e.g., Chemical Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994). Nor can the agency infer facts not in the record. *See Nat'l Gypsum Co. v. EPA*, 968 F.2d 40, 43-44 (D.C. Cir. 1992); *Natural Res. Defense Council v. EPA*, 859 F.2d 156, 210 (D.C. Cir. 1988).

A reviewing court, as instructed by *State Farm*, "may not supply a reasoned basis for the agency's action that the agency itself has not given." 463 U.S. at 43 (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)). Thus, "[i]t is well established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *State Farm*, 463 U.S. at 50; *see also Chenery Corp.*, 332 U.S. at 196. Furthermore, a court will not seek some hypothetical rational support for the agency's action. A court must review the agency's on-the-record reasoning process. Only a formal statement of reasons from the agency can provide this explanation, not a *post hoc* rationalization, or agency counsel's in-court reasoning. *See, e.g., Burlington Truck Lines, Inc.*, 371 U.S. at 168-69; *Am. Petroleum Inst.*, 541 F. Supp. 2d at 185; *Ad hoc Metals Coalition*, 227 F. Supp. 2d at 137.

Arbitrary and capricious review, although deferential, is not a rubber stamp. A court is obligated to undertake "a thorough, probing, in-depth review" and a "searching and careful" inquiry into the agency's record. *See Overton Park*, 401 U.S. at 415-416. The "arbitrary or capricious" standard requires an agency's action to be supported by the *facts in the record*, for a decision without a factual basis is an inherently arbitrary one. Thus, agency action must be set aside as arbitrary if it is unsupported by "substantial evidence." *Ass'n of Data Processing v. Bd. of Governors*, 745 F.2d 677, 683 (D.C. Cir. 1984).

2. EPA failed to make the threshold determination of toxicological significance as expressly required by the applicable regulation.

The SSURO states that Impurity X is a substance or class of substances generally "known to be of toxicological significance." App. at 72. That single amorphous statement, however, which forms the foundation for the SSURO, has no meaning under the applicable regulations, and even if true, is legally insufficient to impose any legal obligation on AMVAC under 40 C.F.R. § 158.320(c), or under any of the other provisions of 40 C.F.R. Part 158, Subpart D.

Section 158.320(c) expressly provides that "[f]or each impurity *associated with* the active ingredient that is *determined by EPA to be toxicologically significant*," the impurity must be included on the CSF (emphasis added). EPA's assertion of general "know[ledge]" is not a proper or a legally defensible substitute for the specific prior "determination" by EPA that Section 158.320(c) requires. *See, e.g., Carlton*, 26 F. Supp. 2d at 108-09. EPA cannot sanction AMVAC for failing to comply with a standard relied upon by the agency but not shared with the regulated public, especially where, as here: (1) EPA's regulation expressly requires the agency to make a "determination" of toxicological significance in the first instance; and (2) EPA conducted a preliminary review of AMVAC's 6(a)(2) submission, decided only a routine, non-expedited review was even recommended, and approved the CSF for the product on two subsequent

occasions, knowing that the product contained Impurity X, but that Impurity X was not listed in the CSF. *See Satellite Broad. Co., Inc. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987) ("Traditional concepts of due process incorporated into administrative law preclude an agency from penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule."); *General Elec. Co. v. EPA*, 53 F.3d 1324, 1328 (D.C. Cir. 1995) ("The due process clause thus prevents deference [to the agency's interpretation of its regulations] from validating the application of a regulation that fails to give fair warning of the conduct it prohibits or requires.") (indications of quotation omitted); *see also United States v. Chrysler Corp.*, 158 F.3d 1350, 1354-57 (D.C. Cir. 1998) (holding that agency failed to provide fair notice of specific requirements of compliance testing and government therefore could not seek an automobile recall on the ground that Chrysler had failed to properly perform testing).

The "record" does not contain a single document demonstrating that *EPA* made the prerequisite "determination," as required by 40 C.F.R. § 158.320(c), that Impurity X is "toxicologically significant" at levels present in Technical Grade PCNB such that AMVAC would be required to identify that substance in an amended CSF. Absent actual record support that EPA made the necessary, prerequisite determination that Impurity X is "toxicologically significant" prior to issuing the SSURO, the order cannot stand and must be vacated.

Additionally, EPA's use of the single amorphous phrase "known to be" in lieu of any actual EPA determination under 40 C.F.R. § 158.320(c) highlights the lack of notice that AMVAC had that somehow, in an instant, its previously approved CSF is no longer valid, and that its products, manufactured under an approved CSF prior to EPA's statement, are suddenly and retroactively out of compliance with FIFRA. EPA's decision to severely and retroactively sanction AMVAC for this alleged omission without any prior notice to AMVAC is an

extraordinary abuse of the authority granted to EPA to issue SSUROs by FIFRA Section 13(a), 7 U.S.C. § 136k(a).

3. EPA cannot, as a matter of law, rely upon a 1988 regulatory preamble as its "determination" that Impurity X is of toxicological significance.

EPA contended for the first time during the TRO proceeding in this matter that several sentences contained in a preamble to a 1988 rule, which was never mentioned until this proceeding was instituted, is its determination of "toxicological significance." The sentences in the preamble purport to identify "classes of impurities of toxicological *concern*." App. at 154.[24] EPA claims that Impurity X falls within this list. App. at 154, 53 Fed. Reg. 15,952, 15,973 (May 4, 1988).

EPA's reliance on the 1988 preamble fails for several reasons. First, the SSURO, on its face, does not purport to rely upon any determination *by EPA* that the agency might have made through the 1988 preamble. App. at 70-73. Indeed, the 1988 preamble is not even listed in EPA's certified record index, nor is there anything in the record that connects that preamble to a purported determination of toxicological significance by EPA as it relates to AMVAC's product.

Second, if the 1988 preamble constitutes a binding "determination" of blanket applicability that Impurity X is of toxicological significance for all registered products and at all levels as of 1988, as EPA appears now to be contending, and that no further action or determination needs to be made, then it constitutes an invalid legislative rule that should have been issued for notice and comment rulemaking under 5 U.S.C. § 553. Court precedents are clear that an agency cannot rely on a non-disclosed basis for taking action. *See General Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002) (where an agency gives its own pronouncement binding

[24] The specific language from the 1988 preamble is not set forth in this brief as it could reveal the identity of Impurity X.

effect, that pronouncement is a legislative rule requiring notice and comment); *Nat'l Family Planning and Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227, 299 (D.C. Cir. 1992) (agency's rulemaking was legislative, and thus must have complied with notice-and-comment requirements of Section 553, where agency "intend[ed] to grant rights, impose obligations, or produce other significant effects on private interests"); *Penobscot Indian Nation v. United States Dep't of Housing and Urban Dev.*, 539 F. Supp. 2d 40, 48 (D.D.C. 2008) (Friedman, J.) (by failing to include in a proposed rule a study the agency relied upon in the final rule, "plaintiffs … were deprived of any meaningful opportunity to comment on what became the centerpiece of the rationale underlying the Final Rule."). It cannot be disputed that the language in the 1988 preamble upon which EPA now purports to rely has not been subject to notice and comment and, according to EPA, imposes a legal obligation on AMVAC for which it is now being sanctioned.[25]

Third, even if EPA's reliance on the 1988 preamble after issuance of the SSURO is merely an "interpretation" of the promulgated rule, this would represent a significant reversal in the agency's interpretation of its regulation without prior notice and comment. *See Alaska Prof'l Hunters Ass'n, Inc. v. FAA*, 177 F.3d 1030, 1033-34 (D.C. Cir. 1999) (requiring notice and comment before the FAA could reverse a decades-old interpretation of its commercial pilot regulations in Alaska); *Ass'n of Am. R.R. v. Dep't of Transp.*, 198 F.3d 944, 950 (D.C. Cir. 1999) (recognizing general requirement of notice and comment before revising established rules, but

[25] The 1988 preamble related to a rule first proposed in 1984. In the preamble to the 1984 proposed rule, EPA specifically discussed its interpretation of "toxicological significance" and made it clear that it would apply it on a case-by-case basis using qualitative and quantitative analysis. "**The second group would be identified on a case-by-case basis, taking into account information on the amount of the ingredient and on the toxicity of the impurity or compounds having a similar chemical structure."** EPA, Pesticide Registration and Classification Procedures, Proposed Rule, 49 Fed. Reg. 37916, 37928 (Sept. 26, 1984) (emphasis added).

permitting an initial period of revision before rules become established); *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997) ("Once an agency gives its regulation an interpretation, it can only change that interpretation … through the process of notice and comment rulemaking."). An agency may not rely on matters of public record after the fact, but must explain how they support the decision at the time the decision is made. *Am. Petroleum Inst.*, 541 F. Supp. 2d at 184 (agency failed to explain why case law supported its position).

EPA decided in 1993 that the presence of Impurity X merited only a routine non-expedited review. App. at 112. It later approved AMVAC's CSF for its Technical Grade PCNB product in 1998 and again in 2005 knowing that Impurity X was present in trace amounts. App. at 115, 120. Those approvals required that EPA expressly determine that the composition was correct, and that the product as manufactured was not in violation of any provision of FIFRA, including FIFRA Section 12(a)(1)(C), which EPA now claims that the product violates. *See* 7 U.S.C. § 136a(c)(5). As explained above, EPA's approvals necessarily required a determination that Impurity X did not have to be identified in the CSF. The agency did not determine that it was toxicologically significant. EPA now claims that Impurity X must be identified because it is toxicologically significant based on the 1988 preamble (or possibly some other non-disclosed basis). This represents a reversal of the agency's prior interpretation of 40 C.F.R. § 158.320(c) without notice and comment, or any explanation as to why it is reversing that position and applying it retroactively. Such action is not permitted. *State Farm*, 463 U.S. at 42 ("an agency changing its course … is obligated to provide a reasoned analysis for the change"); *Jicarilla Apache Nation v. United States Dep't of Interior*, 613 F.3d 1112, 1120 (D.C. Cir. 2010) ("We have held that 'reasoned decision making … necessarily requires the agency to acknowledge and

provide an adequate explanation for its departure from established precedent,' and an agency that neglects to do so acts arbitrarily and capriciously"); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970) ("if an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute.").

Fourth, the list of categories of substances identified as being of "toxicological *concern*" in the 1988 preamble does not by itself constitute a proper "determination" by EPA under 40 C.F.R. § 158.320(c) that particular levels of individual compounds in these classes are "toxicologically significant." EPA knows how to make the prerequisite "determination" of toxicological significance and has expressly done so in the past. This is what happened in Pesticide Regulation (PR) Notice 96-8. App. at 99-107. There, EPA announced that it would consider specific substances to be "toxicologically significant" at specific levels. EPA issued this generic interpretation to "[s]et a clear standard that can be readily applied by EPA/States and the regulated industry alike." Language regarding substances of "toxicological concern" buried in a couple of sentences in a lengthy preamble to a final regulation is far different than a Pesticide Registration Notice that makes specific determinations of toxicological significance.

4. EPA failed to consider AMVAC's 1993 6(a)(2) submission and the agency's own preliminary evaluation of that submission, rendering the SSURO arbitrary and capricious.

In 1993, EPA received and reviewed AMVAC's submission indicating the presence of Impurity X in its Technical Grade PCNB. App. at 78. With this information in hand, and having decided that the presence of what the agency itself called a "known contaminant" merited routine non-expedited review, EPA subsequently approved the CSF for AMVAC's Technical Grade PCNB on two separate occasions. App. at 115, 120. The current EPA-approved CSF for AMVAC's PCNB product includes enforceable certified limits for a number of impurities other than the trace amounts of Impurity X that are at issue here. App. at 119. Had EPA thought that

Impurity X was "toxicologically significant," within the meaning of 40 C.F.R. § 158.320(c), it would have followed a similar path in the context of either of these registration submissions. *Cf. BB&L, Inc. v. NLRB*, 52 F.3d 366, 369 (D.C. Cir. 1995) (*per curiam*) (agency acted arbitrarily and capriciously where it "ignore[d] its own relevant precedent"). The record contains no evidence that EPA considered AMVAC's 1993 6(a)(2) submission and the agency's own review of that submission before issuing the SSURO. Thus the agency has failed to consider an important aspect of the problem and has offered an explanation for its decision that runs counter to the evidence that was, or should have been, before the agency decisionmaker. *See State Farm*, 463 U.S. at 43; *Carlton*, 26 F. Supp. 2d at 107.

5. There was no violation of FIFRA to support the issuance of the SSURO.

FIFRA only permits a SSURO to be issued if there is a violation of FIFRA. *See* 7 U.S.C. § 136k. There can be no violation of FIFRA without a determination by EPA that Impurity X, as it exists in AMVAC's Technical Grade PCNB product, is toxicologically significant. A comment by the agency that Impurity X is "known to be" toxicologically significant in *other* contexts is not a "determination" that it is so either under FIFRA or with respect to AMVAC's Technical Grade PCNB product. AMVAC's PCNB product is entirely consistent with its current registration and CSF, which was approved by EPA knowing full well that Impurity X was present. The possibility that the agency may *now* want AMVAC to include Impurity X in its CSF does not alter the undisputed fact that the product is in full conformity with its current EPA-approved registration and CSF.

6. Issuance of a SSURO was contrary to law.

As discussed in Section III.A above, EPA's decision to use the SSURO to address a purported deficiency in the terms of AMVAC's EPA-approved registration for Technical PCNB

directly undermines the procedures required by FIFRA Section 6, which were created for precisely this purpose. The criteria for cancellation established by FIFRA § 6(b), 7 U.S.C. § 136d(b), are the same as the criteria the agency applies when it grants initial registration. It is clear that cancellation is the appropriate remedy when EPA determines that the standard for registration of a pesticide is no longer met. *Envtl. Defense Fund, Inc. v. EPA*, 465 F.2d 528, 532 (D.C. Cir. 1972), citing *Envtl. Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584 (D.C. Cir. 1971).

If the position that EPA has taken in the SSURO is correct, EPA is presumably arguing that AMVAC has been in violation of the requirement to identify Impurity X at least since AMVAC submitted information on Impurity X in 1993, notwithstanding EPA's subsequent actions approving the Registration. Adjudicative orders such as a SSURO may not apply a legal interpretation retroactively if such application results in manifest injustice. *See, e.g., Epilepsy Found. of Northeast Ohio v. NLRB*, 268 F.3d 1095, 1103 (D.C. Cir. 2001); *Cassell v. FCC*, 154 F.3d 478, 486 (D.C. Cir. 1998); *Clark-Cowlitz Joint Operating Agency v. FERC*, 826 F.2d 1074 (D.C. Cir. 1987). Because AMVAC relied on EPA's previous approvals and determinations with respect to its formula (especially after AMVAC submitted the 6(a)(2) notice disclosing the presence of Impurity X), to permit EPA to change course at the moment it issued a sanction against AMVAC would cause "concerns grounded in notions of equity and fairness." *Clark-Cowlitz*, 826 F.2d at 1082 n.6.

IV. CONCLUSION AND RELIEF REQUESTED[26]

EPA has failed to provide AMVAC with notice and an opportunity to be heard with respect to the revocation of a license that AMVAC properly held for over two decades. Using a

[26] At the TRO hearing, the parties agreed to merge the briefing on preliminary injunctive relief with briefing on the merits issues. AMVAC does not waive, and expressly reserves, its right to appeal Judge Roberts' ruling with respect to the factors for injunctive relief.

SSURO as a surrogate for revoking a registration or suspending its use violates FIFRA and undermines the entire registration process. AMVAC followed the process precisely and notified the agency of Impurity X. EPA acted on its various applications, never once even hinting that the CSF was deficient. Using a SSURO in such manner without first providing prior notice and opportunity to be heard also violates Section 558 of the APA and the Fifth Amendment to the U.S. Constitution. For the foregoing reasons, this Court should hold that the SSURO was issued in a manner that was arbitrary, capricious, and inconsistent with law, and consequently reverse and vacate the SSURO. Moreover, because AMVAC has succeeded on the merits, because there is no adequate remedy at law for the losses suffered by AMVAC, and because the balance of hardships favors the granting of injunctive relief, this Court should immediately enjoin EPA from enforcing the SSURO.

Respectfully submitted,

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