In re FIFRA Section 3(c)(2)(B) Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration	)	
AMVAC Chemical Corporation; Grower-Shipper Association of Central California; J&D Produce; Ratto Bros., Inc.; and Huntington Farms, **Petitioners.**	)	**Docket No. FIFRA-HQ-2022-0002**

PETITIONER GROWER GROUP'S
POST-HEARING REPLY BRIEF

April 21, 2023

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I. INTRODUCTION

Pursuant to the Post-Hearing Scheduling Order dated March 17, 2023, the Grower-Shipper Association of Central California, J&D Produce, Ratto Bros., Inc., and Huntington Farms (collectively, the "Grower Group") respectfully submit this Post-Hearing Reply Brief addressing the terms of the Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate Technical Registration (EPA Reg. No. 5481-495) (the "NOITS").

II. ARGUMENT

A. OPP Continues to Misrepresent the EAB's Determinations Relevant to the Existing Stocks Provision of the NOITS

Respondent the U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs ("OPP"), continues to assert that: (1) the Environmental Appeals Board ("EAB") reached a decision on the existing stocks provision in the NOITS; and (2) the substance of that "decision" is that the EAB has "no issue" with it. Res. Post-Hrg. Br. at 14. Neither assertion has any basis.

The EAB's Decision and Remand Order is clear that, *before* the question of existing stocks can be addressed, the Presiding Officer must apply the appropriate standard concerning AMVAC's efforts to respond to the DCI:

> Because the Board concludes that the case must be remanded to the ALJ to apply the appropriate legal standard and hold a hearing, review of the existing stocks determination at this stage is premature. The Board therefore remands the case to the ALJ to first determine whether AMVAC failed to take appropriate steps to secure the data to fulfill each of the twenty listed requirements, based on the legal standard discussed above and then, if the ALJ finds a basis for the suspension, whether the existing stocks provision of the DCPA NOITS is consistent with FIFRA.

In Re AMVAC Chemical Corporation, 18 E.A.D. 769, 770-71 (EAB 2022) ("Remand Order"). Because the EAB found that the appropriate standard had not been applied to AMVAC's efforts

to respond to the DCI, the Board remanded this matter without addressing whether the existing stocks provision in the NOITS is reasonable and consistent with FIFRA. *Id.*; *see id.* at 796 n. 14 ("The Board takes no position in this order with respect to any ruling by the ALJ on any of these issues on remand").

Importantly, however, the Remand Order is not without guidance concerning the terms of the existing stocks provision in the NOITS. The EAB determined that OPP's approach which also is reflected in the Order on Motion for Accelerated Decision ("MAD Order") (Dkt. No. 28) – that the only way to avoid suspension is to submit all data required[1] – is contrary to the statutory standard. Remand Order, 18 E.A.D. at 770. Rather, FIFRA requires a hearing "to develop an adequate record to reach a conclusion as to whether AMVAC failed to take appropriate steps to secure the data …." *Id.* Thus, basing an existing stocks determination solely on whether the registrant submitted "all data required" without evaluating the particular facts and circumstances likewise would be inconsistent with FIFRA.

B. The Agency's Evolving Justification for the Existing Stocks Provision in the NOITS Remains Unsupported

Under FIFRA § 6, "[t]he Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended … to such extent, under such considerations, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of [FIFRA]." 7 U.S.C. § 136d(a)(1). In this case, OPP explained in the NOITS and the Federal Register Notice announcing it that, "due to the lack of [a final CTA study], the Agency is not able to complete a scientifically robust and defensible human health risk assessment." JX 1 at 1; 87 Fed. Reg. 25262, 25263 (April 28, 2022) (JX 2). In

[1] *See* MAD Order at 34 ("the fastest and surest way to limit the economic harm that AMVAC and the growers may suffer from the suspension is for AMVAC to submit all of the data to EPA that it has requested").

testimony, OPP affirmed that there was "uncertainty" in risk because (as of the date of the NOITS) the final CTA study had not been submitted and that "consideration of uncertainty" arising from the lack of the final CTA study was "the reason" for the existing stocks provision in the NOITS:

> Where the risk picture is so uncertain that EPA cannot even make conservative estimates, not allowing existing stocks to continue to be sold or used by the registrant after issuance of a NOITS is fully consistent with FIFRA's goals to protect humans and the environment from unreasonable adverse effects. In the case of the NOITS for DCPA, *consideration of this uncertainty was **the** reason behind the existing stocks provisions the Agency put forward*.

RX 27 at 7-8 (Bloom) (emphasis added); JX 1 ("due to the lack of data examining the fetal thyroid toxicity of DCPA, the Agency is not able to complete a scientifically robust and defensible human health risk assessment [because] [a]pplying an uncertainty factor … may not account for these missing data …"). As was established even prior to the hearing, however, AMVAC submitted the final CTA study in June 2022 and, in October 2022, OPP indicated that requirement for the CTA study in the DCI had been satisfied. PAX 95 ¶ 144 (Jonynas); Dkt. No. 34 at 2; *see also* Tr. 202:12-14 (OPP objects to the relevance of testimony concerning the CTA study on the grounds that it "consider[s] [the requirement] satisfied").

Given that the "the reason behind the existing stocks provisions the Agency put forward"[2] was eliminated months ago, OPP turns to a new justification in its Post-Hearing Brief. Thus, absent from OPP's Brief is *any* mention of the CTA study, the testimony OPP offered at the hearing related to the existing stocks provision, or the "uncertain risks" that it previously identified as the sole consideration for the existing stocks provision in the NOITS. In short, OPP has completely abandoned the very consideration its own witness testified was "the reason

[2] RX 27 at 8 (Bloom).

behind the existing stocks provisions the Agency put forward." RX 27 at 8 (Bloom). OPP now proposes that incentivizing registrants to submit required data is the consideration against which the existing stocks provision in the NOITS should be evaluated.

Specifically, OPP now posits (without citation) "that suspension under FIFRA Section 3(c)(2)(B) is intended to serve as an incentive for the submission of outstanding data [and that] [t]he existing stocks provisions of the NOITS are clearly rational when viewed in the context of that incentive structure." Res. Post Hrg. Br. at 16. This assertion is entirely theoretical and unconnected to any facts or evidence related to the existing stocks provision in the NOITS. For example, OPP makes no effort to tie it evidence presented at the hearing and, more significantly, fails to identify the standard to be applied with regard to the NOITS to effectuate this incentive. Moreover, to the extent that it is OPP's position that there is some standard against which to measure whether or when an existing stocks provisions may incentivize certain behavior, that standard also cannot be divined from the facts here since, as noted, OPP's own testimony establishes that incentivizing submission of data was *not* the consideration for the existing stocks provision in the NOITS.

Critically, OPP's post-hoc adoption of a justification of the existing stocks provision in the NOITS to incentivize submission of DCI data appears to be based on the unstated premise that the Agency may suspend a registration solely due to a registrant's failure to submit data. However, that is the very approach the EAB rejected. As noted, the MAD Order posited that the existing stocks provision "gives … effect to the statutory deadline for review" because the registrant must "submit *all* of the data to EPA that it has requested" to avoid suspension. MAD Order at 34 (emphasis in original). However, the EAB rejected application of an all-or-nothing standard for suspension under FIFRA, directing instead that analysis must consider whether, for

each item of data at issue, the registrant took appropriate steps to secure it. Remand Order, 18 E.A.D. at 770, 787-89. As such, OPP's effort to justify the existing stocks provision as an incentive for the registrant to submit all the data "as quickly as possible,"[3] suffers this same fatal, legal defect and therefore is inconsistent with FIFRA. 7 U.S.C. § 13a(c)(2)(B)(iv).

Instead, the statutory standard of "appropriate steps" necessarily is specific to each data call-in to which it is applied and requires a fact-intensive inquiry of the particular data requirements at issue, the registrant's efforts with regard to the same and (as well illustrated by this matter) communications and dialogue between the Agency and the registrant related to each data item. *See* Remand Order, E.A.D. at 793 ("[O]n remand, the ALJ must independently review the evidence relevant to whether AMVAC took appropriate steps without special deference to the Pesticide Program's conclusions"). Assuming *arguendo* that the Presiding Officer finds that AMVAC did not take "appropriate steps" with respect to a data requirement in the DCI, OPP makes no attempt to explain how the existing stocks provision in the NOITS is necessary to incentivize AMVAC – or another registrant addressing a different data call-in with different data requirements – to take different or further steps.[4] Indeed, studies to address the data requirements that OPP contends remain at issue already are underway, and many of the requirements have been satisfied since the issuance of the NOITS. *See, e.g.*, PAX 93 ¶¶ 37-42 (identifying studies that are underway); Dkt. No. 44 (narrowing scope of data requirements at issue for the suspension). As such, the record in this matter provides no support for the

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[3] Res. Post-Hrg. Br. at 17.

[4] OPP also does not identify what those steps might be. To the extent the unstated step is simply to submit the data, again, that is contrary to the legal standard to be applied. *See* Remand Order, 18 E.A.D. at 770 ("Because the ALJ limited the inquiry to whether AMVAC had submitted the required data, omitting analysis of whether AMVAC had taken appropriate steps to secure the data, the ALJ misconstrued the statute and failed to apply the correct legal standard").

proposition that the existing stocks provision in the NOITS is necessary to prevent AMVAC from discontinuing those studies. In short, OPP's latest effort to justify the existing stocks provision in the NOITS suffers from the same defects as its prior effort: it is unsupported by the evidence at the hearing; makes no sense under those facts; and appears to be based on flawed analysis that the EAB rejected as inconsistent with FIFRA.

C. FIFRA § 3(c)(2)(B)(iv)'s Authorization for Third Party Objections is Neither "New" nor as Narrow as EPA Posits

Contrary to OPP's assertion, the Grower's position that they have a right to request a hearing concerning the impact of the existing stocks provision of the NOITS is not "new." Res. Post-Hrg. Br. at 15, 16. The right of the Growers, as "person[s] adversely affected," to request a hearing is found in the plain terms of the FIFRA § 3(c)(2)(B)(iv), the NOITS and the Federal Register notice announcing the NOITS. 7 U.S.C. § 136a(c)(2)(B)(iv); JX 1-2. In their initial Request for a Hearing and Objection, the Growers identified the significantly adverse impact the existing stocks provision in the NOITS would generate. *See, e.g.,* Dkt. No. 3 at 2 ("The Grower Group – and ultimately American consumers – will suffer significant adverse impacts if the registration for DCPA is suspended. Therefore, as permitted by the NOITS, the Grower Group submits this Objections and Request for a Hearing on the NOITS."); *see also* Pet. AMVAC Opp. to MAD at 16 (Dkt. No. 19).[5] Thereafter, this matter initially was decided without a hearing on Respondent's MAD, then reversed and remanded by the EAB, and, on remand, the Presiding Officer requested that the parties limit their pre-hearing briefs to identified issues that did not include existing stocks (although OPP addressed existing stocks notwithstanding the Presiding

[5] The Growers also address these issues in their Notice of Exceptions and Appeal Brief submitted to the EAB.

Officer's briefing order). Dkt. Nos. 28, 33. As such, the Growers' position and argument is not new, and basis of OPP's characterization of their arguments as such is unclear.

Moreover, it is OPP that attempts to raise a new argument related to the scope of the Growers' objections in this matter, although OPP also undermines its own argument. OPP now suggests for the first time that the permissible scope of objections the Growers may raise is limited to restrictions on their ability to use existing stocks of end use products containing DCPA. Res. Post-Hrg. Br. at 17, 18. Thus, according to OPP, consideration of market and economic impacts of the existing stocks provision in the NOITS fall outside the relevant considerations of the Growers' hearing request and objections. *Id.* However, OPP almost immediately contradicts itself by conceding that "FIFRA Section 3(c)(2)(B)'s provision for 'a person adversely affected' to request a hearing makes no assumption as to the interests or potential evidence that might be offered by a non-registrant petitioner." *Id*. at 17-18. The Growers agree. FIFRA Section 3(c)(2)(B)(iv) does not limit the issues "a person adversely affected" may raise to demonstrate that "the Administrator's determination with respect to existing stocks" is not consistent with FIFRA. 7 U.S.C. § 136a(c)(2)(B)(iv). As such, OPP's contention that undisputed evidence offered by the Growers can and should be ignored finds no legal support. *Id.*

OPP also accuses Petitioners of conflating the provisions of the Existing Stocks Policy concerning amended or cancelled registrations that address a risk/benefit analysis with those addressing suspension. Again, however, it was OPP that based the existing stocks provision in the NOITS on concerns of risk – albeit "uncertain risks" – but then sought to use the Existing Stocks Policy justify its position even though that Policy does not permit consideration of risks in isolation from benefits. *See* Pet. Growers' Post-Hrg. Br. at 11, 15-16. More importantly,

FIFRA provides no support for the proposition that considerations underlying existing stocks require a risk/benefit analysis for cancellation but not suspension.

Finally, OPP's only response to the adverse impacts identified by the Growers that arise from the unique market structure in supply and distribution of DCPA is to assert "that it is not uncommon for a single company to control the entire United States market for a given pesticide product, including both technical and end-use products." Res. Post-Hrg. Br. at 15. This assertion is based on a proffer of new evidence (without requesting leave to do so) concerning three products. There is no information in the record about these products and their registrations, or their relevance to this proceeding. For example, OPP offered no testimony or evidence at the hearing as to whether these three products are comparable to DCPA and relevant to the facts related to the market and uses for DCPA demonstrated at the hearing because, by way of example, they serve a critical need that cannot replaced by other products or means of crop protection. *Compare* PGX 7A ¶ 13 (Fennimore) ("DCPA is an essential foundational tool for effective and economical control of yield-robbing grasses and broadleaf weeds in onions and small acreage brassica crops"; PGX 8 ¶ 9 (Smith) ("Because of the broad range of weeds controlled by DCPA it is the key preemergent herbicide to [] economically control grasses in weeds in brassica crops"); PGX 7A at ¶ 16 (Fennimore) ¶¶ 19-27 (discussing lack of replacements for DCPA's uses); PGX 8 ¶ 13 (Smith) ("There is no another preemergent herbicide registered for use on onions that provides the same efficacy as DCPA"); PGX 3 at 51-55 (Tables 20-24) (contrasting spectrum of control for DCPA and other herbicides for annual and perennial weeds in onions and garlic); *id*. at 50-51 ("none of the other herbicides provide the same spectrum of control as [DCPA] in cole crops or onions"); PGX 6 ¶ 34 (Valadez) ¶¶ 35-40 (explaining why mechanical and hand weeding are not available, viable and/or economical

alternatives to DCPA); PGX 8 ¶ 11 (Smith) (mechanical weeding of onions is not possible due to onion production systems); PGX 6 ¶ 35 (Valadez) ("current technology for mechanical weeding does not allow removal of weeds when they cover the commercial crop during a time of critical growth").[6]

The relevance of the three products OPP proffers also is unclear because OPP does not indicate if any of them have been suspect to suspension and, if so, how the considerations in the applicable existing stocks provisions compare to those in the DCPA NOITS. Finally, at the most basic level, OPP provides no basis to support its bald assertion that the existence of three products where it contends one company "controls" the market for that pesticide means that the situation with DCPA is not uncommon or is inconsistent with AMVAC's status as the sole registrant for DCPA technical and end use products being unique.[7]

III. CONCLUSION

In the event that that the Presiding Officer determines that AMVAC failed to "take appropriate steps to secure the data required" by the DCI, the Presiding Officer should issue an Initial Decision concluding that, at a minimum, the portion of the NOITS concerning existing stocks that prohibits AMVAC from formulating stocks of DCPA technical in its possession at the time of a suspension into end use products following the effective date of the suspension is inconsistent with FIFRA.

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[6] OPP also asserts that "there is no legal impediment" to a third-party obtaining a technical or end use registration DCPA registration. Res. Post-Hrg. Br. at 17. As with its post-hoc attempt to justify the existing stocks provision in the NOITS as incentivizing submission of DCI data, OPP's effort to discount the unique market structure for DCPA also is entirely theoretical and unconnected to any facts or evidence offered at the hearing. OPP has supplied no factual basis to conclude that it is possible or likely that a third party will apply for and then receive a DCPA registration and, if so, that the timing would be such that this new, unidentified registrant could mitigate the impact the existing stocks provision in the NOITS will have on Growers.

[7] The Growers adopt the arguments in AMVAC's Post-Hearing Reply Brief concerning existing stocks, including issues not otherwise addressed herein.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2023, the foregoing **Petitioner Grower Group's Post-Hearing Reply Brief**, was submitted to the following in the manner indicated below.

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