BEFORE THE ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

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; Sunheaven Farms, LLC; J&D Produce; Ratto Bros., Inc.; and Huntington Farms,	)
Petitioners-Appellants	)
Dkt No. FIFRA-HQ-2022-0002	)

NOTICE OF EXCEPTIONS AND APPEAL BRIEF OF THE GROWER GROUP: THE GROWER-SHIPPER ASSOCIATION OF CENTRAL CALIFORNIA, J&D PRODUCE, RATTO BROS., INC., AND HUNTINGTON FARMS

July 21, 2022

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NOTICE OF EXCEPTIONS

The Grower-Shipper Association of Central California, J&D Produce, Ratto Bros., Inc., and Huntington Farms (collectively, the "Grower Group") file this Notice of Exceptions and request that the Environmental Appeals Board ("EAB") review and reverse the July 1, 2022, Order on Respondent's Motion for Accelerated Decision concerning disposition of existing stocks of Dimethyl Tetrachloroterephthalate ("DCPA") (EPA Reg. No. 5481-495) issued by the Office of Administrative Law Judges in the above-captioned case, FIFRA-HQ-2022-0002, Dkt. No. 28 (the "Order") concerning the Notice of Intent to Suspend [DCPA] Technical Registration, 87 Fed. Reg. 25262 (Apr. 28, 2022) (the "NOITS").

APPEAL BRIEF

I. INTRODUCTION

The Grower Group appeals the determination in the Order that the Administrator's determination regarding existing stocks is reasonable, rational and consistent with FIFRA.

II. STANDARD OF REVIEW

The Grower Group incorporates by reference the Standard of Review provided in the Exceptions and Appeal Brief of AMVAC.

III. BACKGROUND

A. Factual and Procedural Background

The Grower Group incorporates the statement of facts and procedural background concerning the pesticide DCPA and this matter set forth in the Notice of Exceptions and Appeal Brief Submitted by AMVAC Chemical Corporation.

B. Legal Framework Concerning Existing Stocks

FIFRA § 3(c)(2)(B)(iv) authorizes the Administrator to include reasonable provisions concerning the disposition of its existing stocks of that pesticide, and to allow continued distribution, sale and use of existing stocks of a pesticide whose registration has been suspended due to a registrant's alleged failure to comply with a data call-in. 7 U.S.C. § 136(a)(c)(2)(B)(iv). Although the Administrator has discretion in this regard, its discretion is not unbounded. Any provisions imposing limitations on existing stocks must be appropriate, rational and consistent with FIFRA. *Id.*

In 1991, the Agency published a Statement of Policy concerning Existing Stocks of Pesticide Products (the "Policy") concerning "whether, and under what conditions, the Agency will permit the continued sale, distribution and use of existing stocks of pesticide products whose registrations under [FIFRA] are amended, cancelled, or suspended." 56 Fed. Reg. 29362 (June 26, 1991). As this Policy acknowledges, the determination with respect to existing stocks of an amended, suspending or cancelled pesticide registration inherently is a fact specific inquiry. *Id.* ("This Statement summarizes the policies that will generally guide EPA in making individual decisions [concerning existing stocks]").

In this regard, the Policy distinguishes between several specific situations. For example, "[w]here there are no significant risk concerns associated with the cancellation of a pesticide, the Agency will generally allow unlimited use of existing stocks …." *Id.* If the Agency has significant risk concerns associated with a cancellation action, determinations related to existing stocks "will generally require a risk/benefit analysis …." *Id.* In particular, that analysis may include an evaluation of whether "the social, economic, and environmental benefits associated with [the] distribution, sale, or use exceed the social, economic, and environmental risks" of the cancelled pesticide. 56 Fed. Reg. at 29364. Importantly, this "risk/benefit analysis for existing

stocks purposes is somewhat different from the analysis that is performed by the Agency in determining whether or not to cancel a registration." *Id.* For purposes of existing stocks of a cancelled pesticide, the Agency may consider, *inter alia*, the quantity of existing stocks of the cancelled pesticide available; the risks resulting from use of that pesticide; and the benefits resulting from the use of such stocks. *Id.* With respect to the latter, specific considerations include the availability of alternatives, problems with switching to alternatives (if any), and cost and efficacy issues with respect to alternatives. *Id.*

Similarly, the Policy addresses pesticides with suspended registrations under two different scenarios. 56 Fed. Reg. at 29367. First, EPA may suspend a registration based on an imminent hazard. *Id.*; *see* 7 U.S.C. § 136d(c). Second, EPA may suspend a pesticide for failure "to submit data required by the Agency in a timely fashion." 56 Fed. Reg. at 29367; *see* 7 U.S.C. §§ 136b(d)(6), 136b(f)(3). In the case of the former, the Policy applies the same risk/benefit analysis noted above for cancelled registrations; in the case of the latter, the Policy provides that it generally will not place restrictions on the sale, use, or distribution of existing stocks by persons other than the registrant unless risk concerns are identified. 56 Fed. Reg. at 29367.

C. The Agency's Determination Concerning Existing Stocks of DCPA

As to existing stocks of DCPA, the NOITS provides as follows:

> After the suspension becomes final and effective, the registrant subject to this Notice, including all supplemental registrants of the product registrant listed in Attachment I, cannot legally distribute, sell, use (including use to formulate another pesticide product), offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the product listed in Attachment I, except for the purpose of disposal in accordance with all applicable federal, state and local requirements. Any distribution or sale, by the registrant subject to this Notice, of a pesticide whose registration is suspended, is an unlawful act under section 12(a)(1)(A) of FIFRA. Any other violation of the suspension order, including use to formulate

> another pesticide product, is an unlawful act under section 12(a)(2)(J) of FIFRA.

87 Fed. Reg. at 25262. The NOITS and this provision concern only DCPA, the technical grade of the pesticide that is then formulated into an end use product that would be applied by the grower. The registration – and thus distribution, sale and use – of end use products formulated with DCPA are not an express subject of the NOITS, nor are end use products formulated prior to the suspension restricted by the existing stocks provision. Similarly, the existing stocks provision applies only to AMVAC and would not prohibit formulation of existing technical DCPA into end use products by a third party – anyone other than AMVAC – following the suspension. However, for reasons explained below, unique market-based characteristics of this matter indirectly impact the continued availability of end use products formulated with DCPA after the suspension.

The Agency justified its existing stocks provision concerning DCPA in part by noting that "[b]ecause essential data are not available, EPA is unable to determine the magnitude of the risks associated with the continued use of DCPA." Mot. 49 (Dkt. No. 12). The Order likewise focuses on testimony from the Agency arguing that not allowing the registrant to continue to use or sell DCPA after the suspension is consistent with FIFRA due to alleged uncertainty in the "risk picture." Order at 33 (quoting Bloom Statement at 7). In addition to certain requirements for residue data, the Agency focused on a comparative thyroid toxicity study ("CTA") required by the DCI. Mot. at 49 ("EPA lacks the information to determine whether DCPA pesticides may cause unreasonable adverse effects on the environment, especially with respect to possible fetal thyroid effects"); *see also id.* at 32-37 (discussing status of CTA study). Notwithstanding its stated risk concerns, however, the Agency goes on to note that the existing stocks provision allows for the continued sale, distribution and use of end-use products made from AMVAC's

technical DCPA prior to the effective date of the suspension order. Mot. at 48; *see also* Mot. at 39, 48-39 (acknowledged that the provision allows the sale, distribution and use of end-use products formulated *after* the effective date of the suspension using existing stocks of AMVAC technical in the hands of third parties, while only AMVAC is prohibited from doing the same).

IV. ARGUMENT

A. The Existing Stocks Determination is Inconsistent with FIFRA and EPA Policy

A hearing is necessary to evaluate whether the Agency's provisions for existing stocks for DCPA set forth in the NOITS are consistent with FIFRA. As noted, the existing stocks provision allows for the continued sale, distribution and use of end-use products containing DCPA prior to the effective date of the suspension order. The provision also allows the sale, distribution and use of end-use products containing DCPA formulated *after* the effective date of the suspension using existing stocks of AMVAC technical in the hands of third parties.

Ordinarily, this structure would mitigate significant impacts to growers because registrants not subject to the suspension could continue to use existing stocks of the suspended technical for formulate end-use products and supply the market. But here, as AMVAC has explained, end-use products containing DCPA that are sold and distributed to growers are formulated only by AMVAC (*i.e.*, no technical is supplied to third parties). McMahon (AMVAC) Statement at 2 (Dkt. No. 15.03); Verified Written Statement of AMVAC Witness Suneet Ranganath at 1-2 (Dkt. No. 15.06). Thus, after supplies of end-use products formulated by AMVAC prior to a suspension are exhausted (a point in time that can only be roughly established at a hearing), growers will lose *all* access to products containing DCPA.

This critical distinction differentiates this matter from the examples on which the Agency relied in connection with its argument that the NOITS provision is consistent with "historical and

recent practice." Mot. at 2. The Agency pointed to two notices of intent to suspend registrations that have no relevance to this situation. *See id*. at 2, 48 (citing 77 Fed. Reg. 31844 (May 30, 2012), 80 Fed. Reg. 11669 (March 4, 2015)). The basis of the intended suspension in those matters was registrants' failures to submit 90-day or 8-month responses to a data call-in, or failures to submit product performance, chemistry or toxicology data. 77 Fed. Reg. at 11670, 80 Fed. Reg. at 31845-46. More critically, none of those cases appear to involve a situation where the registrant whose registration was to be suspended is *only* company that holds a registration for the technical product to be suspended *and* all end use products formulated from that technical. *See* 77 Fed. Reg. 31844; 80 Fed. Reg. 11669. In other words, the existing stocks provisions on which the Agency relies will not directly or indirectly terminate the supply of all end use products that contain the relevant active ingredients once existing supply of the technical is depleted. Indeed, most of the products identified are particular end use products, not technical products like DCPA. *See id.*

The Agency failed to consider these vital distinctions, and the Order likewise overlooks them. As noted above, AMVAC is the only registrant that formulates DCPA into end use products. Thus, in contrast to the matters relied upon by the Agency, upon the suspension of the DCPA registration, there are no other registrants who can continue to formulate existing technical product into registered end use products for use by growers. Thus, restrictions on AMVAC's ability to use, distribute and sell DPCA under the NOITS effectively also act as a restriction on end use products containing DCPA that have not been formulated as of the date of the suspension.

When the supply of end use products existing as of the date of the suspension is exhausted, growers will lose a critical and irreplaceable crop protection tool. As explained in

sworn testimony submitted by the Grower Group, end use products containing DCPA are essential foundational tools for effective and economical control of certain grasses and broadleaf weeds for onions and small acreage brassica crops. *See generally* Direct Testimony of Stephen A. Fennimore, Ph.D. (Dkt. No. 14); Direct Testimony of Richard Smith (Dkt. No. 14). For certain uses for onions, for example, *there are no other registered herbicides* that could replace the critical role of DCPA. Smith Test. ¶¶ 10-14.

The fact that a market impact will occur solely because of the structure of the supply chain cannot reflect Congress's intent. Indeed, Congress elected to permit not only registrants, but any "person adversely affected by the notice [of intent to suspend]" to obtain a hearing under the Suspension Provision, and this applies equally when the suspension is due to alleged non-compliance with a data call-in. 7 U.S.C. § 136a(c)(2)(B)(iv). The Grower Group's interests merit additional contention here, because the unique nature of the supply chain means that once AMVAC's technical product is suspended no further formulation of end-use products using stocks of technical may occur, which could mitigate the impact of the suspension on critical crops.

B. The Existing Stocks Provision is Improperly Based on "Risk Concerns"

The Order acknowledges the Grower Group's and AMVAC's concerns about the impacts of the existing stocks provision in this matter "may be valid," but dismisses them because "it is impossible to weigh" these concerns against risk concerns based on a lack of data. Order at 34. However, the Order ignores that the primary item of data to which the Agency pointed in its Motion as needed to evaluate risks – the CTA study[1] – was submitted by AMVAC on June 20,

[1] *See* Mot. at 49 ("With respect to DCPA, EPA lacks the information to determine whether DCPA pesticides may cause unreasonable adverse effects on the environment, especially with respect to possible fetal thyroid effects").

2022. Pet. AMVAC's Opp. to Mot. at 40 (MRID 51931701) (Dkt. No. 20).

Further, allowing EPA to remove a product from the market using an existing stocks order under the Suspension Provision of FIFRA § 6 would improperly allow the Agency to sidestep the appropriate proceedings that must be used where there are risk concerns. Here, EPA has explained that its decision to proceed with the suspension was motivated in substantial part by the fact that it has preliminary data suggesting potential thyroid effects from a precursor study to the definitive CTA study. *See, e.g.,* Mot. at 33. Perhaps anticipating the argument that suspension actions under the Suspension Provision are not the method Congress dictated EPA use to vindicate concerns of risk under FIFRA, EPA attempts to shift the narrative from risk to "uncertainty," and the Order appears to accept the argument that uncertainty in the "risk picture" warrants a restriction on existing stocks. Order at 7, 33. Allowing EPA to remove the product from the market using an existing stocks provision, based on vague allegations of uncertainty, particularly when it *already has the definitive study in hand*,[2] violates the holding of *Reckitt Benckiser, Inc. v. Jackson*: EPA cannot avoid conducting a full cancellation hearing when it seeks to remove a product from the market based on risk concerns, by resorting to other mechanisms under FIFRA not intended to address risk concerns. 762 F. Supp. 2d 34, 35 (D.D.C. 2011).[3]

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[2] EPA has now had the final, definitive CTA study in its possession, for a full month since it was submitted on June 20, 2022. If EPA's concerns are truly "uncertainty," it should have been able to at least preliminarily assess whether the CTA study resolves any of that uncertainty.

[3] If the basis of the Agency's existing stocks determination – and the Order's finding that it is consistent with FIFRA – is premised on risk, the ability to obtain review of the alleged risks should not be prejudiced based on EPA's use of the Suspension Provision rather than a cancellation proceeding. The prejudice to the ability to obtain review of the basis for EPA's action has been compounded by the fact that the Order does not even address whether AMVAC acted appropriately in connection with the CTA study. The fact that the risk/uncertainty concerns EPA uses to support the existing stocks restriction relate to a study that the Order does not address further highlights this error.

Moreover, under EPA Policy, consideration of alleged risk concerns in connection with the existing stocks provisions for product suspensions based on a failure to completely satisfy a DCI also is improper. 56 Fed. Reg. at 29367. Where a product registration is suspended based on risk concerns, EPA Policy *requires* that the existing stocks provision include consideration of the benefits of the product including, *inter alia*, the availability (or lack thereof) of alternatives, problems with switching to alternatives (if any), and cost and efficacy issues with respect to alternatives. *Id.* at 29364, 29367. Here, the Agency's and Order's improperly reliance on alleged risk issues is compounded by their failure to even consider benefit issues raised by the Grower Group that should be evaluated under EPA Policy where a suspension is based on risk.

C. The Existing Stocks Provision for DCPA is Irrational and Unreasonable

The Agency's attempts to justify the restrictions on existing stocks based on risk concerns – and the Order's acceptance of this justification – also is irrational and unreasonable. Under the existing stocks provision of the NOITS, if a third party had the ability to formulate end use products from existing stocks of technical, it would not be prohibited from doing so while AMVAC is. There is no difference in "risk" following the suspension if AMVAC is the formulator of the existing technical into end-use product rather than third party which is permitted to do so.

The Order nonetheless concludes that the restriction prohibiting any further formulation of existing stocks of technical by AMVAC is appropriate because "[w]ithout such a suspension order the record suggests that AMVAC may continue to unhurriedly, if at all, provide the requisite studies." Order at 34. To the extent this factual conclusion is material to the decision in the Order, it is erroneous because it improperly resolves inferences against AMVAC (*i.e.*, it assumes that AMVAC's conduct is intentionally or abnormally dilatory). More importantly, it makes no sense. The Grower Group asks only that AMVAC be treated like other third parties

with respect to formulation of end-use products from *existing* technical stock. The Agency and the Order neither consider or supply a reasonable basis why AMVAC's existing stocks of technical DCPA should be treated differently.

V. CONCLUSION

For the reasons set forth above, the Order granting Respondent's Motion for Accelerated Decision was improperly granted. The EAB should remand this matter for a hearing on whether the existing stocks provision of the NOITS is reasonable, rational and consistent with FIFRA.

DATED: July 21, 2022

Respectfully submitted,

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STATEMENT OF COMPLIANCE WITH WORD LIMITATION

I certify that the word count of the forgoing **Petitioner Grower Group's Exceptions and Appeal Brief,** excluding the cover page, table of contents, table of authorities, signature block, this statement of compliance, and the certificate of service contains 2,945 words, as counted by Microsoft Word.

/s/ *Cristen S. Rose*
Cristen S. Rose

CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2022, the foregoing **Petitioner Grower Group's Exceptions and Appeal Brief**, was filed with Environmental Appeals Board (www.EPA.gov/EAB) and was to the following in the manner indicated below.

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