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 BRIEF

April 7, 2023

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I. INTRODUCTION AND SUMMARY

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 Brief addressing the terms of the Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate Technical Registration (EPA Reg. No. 5481-495) (the "NOITS").

Because the Grower Group challenges a portion of the determination of the U.S. Environmental Protection Agency ("EPA" or "Agency") concerning existing stocks in the NOITS, the Presiding Officer need not reach this issue if it is determined that Petitioner AMVAC Chemical Corporation ("AMVAC") took "appropriate steps to secure the data required" by the DCI. If a contrary determination is made, the Grower Group challenges the portion of the existing stocks provision 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. The Grower Group notes, however, that the Agency's admission that any consideration of the impact of existing stocks provision in the NOITS is "irrelevant" (EPA Pre-Hrg. Br. at 27 (Dkt. 48)), raises larger questions about whether it can support any element of the provision, having now conceded that it disregarded a critical inquiry under its own guidance that is also necessary under any reasonable interpretation of the statutory requirement that existing stocks policies be "consistent with" FIFRA.

II. PROCEDURAL BACKGROUND

A. The NOITS and the Existing Stocks Provision

Pursuant to FIFRA § 3(c)(2)(B)(iv), the Agency issued the NOITS dated April 21, 2022 to AMVAC, and it was published in the Federal Register on April 28, 2022. JX 1, 2. As permitted by FIFRA § 3(c)(2)(B)(iv) and the terms of the NOITS, AMVAC and "another person

adversely affected by [the NOITS]" may request a hearing within 30 days of the receipt of the NOITS. JX 2 at 3. The issues to be addressed at such a hearing are (1) whether the registrant "failed to take appropriate steps to secure the data required" and (2) whether the provision regarding the disposition of existing stocks is consistent with FIFRA. FIFRA § 3(c)(2)(B)(iv). As ""interested person[s] adversely affected," the Grower Group requested a hearing to address whether the NOITS provision addressing existing stocks is consistent with FIFRA. Dkt. 3.

The existing stocks provision of 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.

JX 1 at 4-5. This provision concerns only technical grade DCPA (EPA Reg. No. 5481-495), the technical grade of the pesticide that is then formulated into an end use product to be applied by the grower. JX 1. The registration – and thus distribution, sale and use – of end use products formulated with DCPA are not impacted by the NOITS, even if a suspension goes into effect. *See id.* 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. *Id.* Critically here, however, there are no other third parties that hold DCPA technical or end-use registrations, as discussed below.

Ordinarily, an existing stocks provision that applies only the technical active ingredient (and thus prohibits only the technical registrant from formulating technical into end use product)

would mitigate against any adverse impacts on growers and the market because third parties could still formulate the technical into end-use products while the technical registrant's registration was suspended. In this case however, AMVAC established at the hearing – and the Agency does not dispute – that 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). PAX 93 ¶ 14 (McMahon); PAX 96 ¶¶ 6-7 (Ranganath). In other words, market structure for DCPA is not typical, and so a suspension could impact the continued availability of end use products formulated with DCPA in a manner that would not be expected to occur normally.

B. The MAD Order Concerning Existing Stocks

The ALJ granted the Agency's Motion for Accelerated Decision ("MAD") and found the existing stocks provision of the NOITS to be consistent with FIFRA for two reasons. MAD Order (Dkt. 28). The first reason was based on the Agency's contention that the terms of the existing stocks provision were necessary to address "uncertain risks" arising from AMVAC's failure to fully satisfy the data call-in ("DCI," JX 5). *See* MAD Order at 34 ("AMVAC's failure to provide the requisite information to EPA for registration review within the lengthy statutory period provided" prevents the Agency from "weigh[ing] the impact of [Growers' testimony concerning] disruption against the harm, if any, [DCPA's] cumulative use over time may be causing as determined using scientific data"). Second, the MAD Order provided that the existing stocks provision served as deterrence for "dilatory registrants" and incentivized them to provide all required data by the deadline. *Id*. In particular, the MAD Order noted that "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." *Id*. (emphasis in original). As such, and as discussed below, this second justification was based on, and

incorporated, the view that the only way to prevent suspension is to submit all required data, a standard that the Environmental Appeals Board ("EAB") subsequently rejected.

C. The EAB Decision and Remand Order

In its Decision and Remand Order addressing the MAD Order, the EAB found, *inter alia*, "that the ALJ misconstrued and misapplied the statutory standard for granting suspension under FIFRA. *In Re AMVAC Chemical Corporation*, 18 E.A.D. 769, 789-90 (EAB 2022) ("Remand Order"). In particular, the Remand Order rejected application of an all-or-nothing approach to whether all data required in the DCI had been submitted. Instead, the EAB directed as follows:

> FIFRA and its implementing regulations provide an opportunity for a hearing at which the ALJ is required to weigh the evidence and make findings of fact and conclusions of law based on the evidence presented. On remand, the ALJ must independently review the evidence relevant to whether AMVAC took appropriate steps without special deference to the Pesticide Program's conclusions. Furthermore, the ALJ must determine whether AMVAC failed to take appropriate steps with respect to each of the twenty data requirements listed in the notice of intent to suspend. If a suspension were to take effect based on a finding that AMVAC failed to take appropriate steps with respect to fewer than twenty requirements, there would be no legal basis for continuing the suspension after AMVAC complied with those requirements.

Remand Order at 2.

The EAB also made clear that it did *not* reach the question of whether the existing stocks provision in the NOITS was consistent with FIFRA. Rather, the EAB explained that it would be premature to address this provision until the correct legal standard for suspension is applied:

> The Board therefore remands the case to the ALJ to *first* determine whether AMVC 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 is consistent with FIFRA.

Id. at 28 (emphasis added). In other words, the EAB explicitly *did not* address the ultimate issue of whether the existing stocks provision of the NOITS is consistent with FIFRA, and explained that that issue could not be reached until the ALJ applied the correct standard for suspension.

See also id. ("The ALJ Must Review the Existing Stocks Determination *After* Applying the Correct Legal Standard") (emphasis added).

As such, it is remarkable that the Agency asserted in its Prehearing Brief that the EAB "found no issue with the Presiding Officer's conclusions concerning the existing stocks provision of the NOITS,"[1] when the EAB *explicitly* declined to reach that issue. Remand Order at 28. Moreover, to the extent the Presiding Officer relied on the same all-or-nothing standard to justify both the suspension and the existing stocks provision,[2] that flawed analysis must be reconsidered in view of the EAB's findings concerning the correct standard. *See id.* at 2 ("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").

D. The Agency's Effort to Justify the Existing Stocks Provision Based on "Uncertain Risks"

The Agency contends that the DCPA existing stocks provision is it necessary due to uncertainty in the risk picture. In its MAD, the Agency asserted 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." MAD at 49 (Dkt. No. 12). The Agency's concern of "uncertainty" focused on a comparative thyroid toxicity study ("CTA") required by the DCI and EPA's position that it "lacks the information to determine whether DCPA pesticides may cause

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[1] EPA Pre-Hrg. Br. at 27. The issues identified in the Order on Respondent's Motion to Amend Hearing and Scheduling Order (Dkt. 33) on which briefing was requested did not include existing stocks, so the Grower Group did not submit a Pre-Hearing Brief. *See also* AMVAC Pre-Hrg. Br. at 4 n.4 (AMVAC did not address existing stocks in its Prehearing Brief because "[t]he Presiding Officer did not request any prehearing briefing on … the propriety of EPA's Existing Stocks order") (Dkt. 52).

[2] *See* MAD Order at 34 (explaining 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) (emphasis in original).

unreasonable adverse effects on the environment, especially with respect to possible fetal thyroid effects." *Id*.

Although the CTA study had been submitted to the Agency approximately six months prior to the hearing,[3] at the hearing, OPP did not depart from this justification. Thus, whereas the Agency reevaluated the data requirements for which it sought suspension (*see* Dkts. 43, 53), it *never* reevaluated the existing stocks provision related to that suspension, notwithstanding that the only data it identified as reason for that provision had been submitted. In her submitted testimony, for example, Jill Bloom emphasized that the existing stocks terms were based solely on "uncertainty" concerning risks:

> 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 6-8 (Bloom). Ms. Bloom also offered vague and conclusory assertions that the existing stocks provision in the NOITS was "typical for products suspended under FIFRA Section 3(c)(2)(B)" and "similar to provisions from most prior FIFRA Section 3(c)(2)(B) suspension where registrants have failed to submit data in response to EPA DCIs." *Id.* at 7. However, she did not identify *any* suspended products she considered in deeming the DCPA provision "typical," nor did she explain why she concluded that it was "similar" to existing stocks provisions for "most" (but apparently not all) suspensions under FIFRA § 3(c)(2)(B). *See id.* She also did not address whether any of the unidentified other products she may have considered

[3] "The final report for the CTA study was submitted to EPA on June 20, 2022 …." PAX 95 ¶ 144 (Jonynas); *see id.* (amended final report for CTA study submitted on August 5, 2022); Dkt. 34 at 2 (October 2022) (OPP considers DCI data requirement for CTA study to be satisfied).

presented the same unique circumstances present here that are discussed more fully below. These include the undisputed facts that: (1) DCPA addresses critical grower needs that cannot be met by alternative products; (2) AMVAC is the sole registrant and only entity that can formulate it into end use products; and (3) the terms of the DCPA existing stocks provision effectively mean that access and supply of a critical crop protection product will end. She also did not explain whether, why or how the uncertain risks that were "the reason" for the existing stocks provision in the NOITS makes it "typical" or "similar" to the Agency's treatment concerning continued sale of other unidentified products. *Id.*

E. The Agency Does Not Dispute Any of the Significant, Adverse Impacts that will Result from the Existing Stocks Provision in the NOITS

The facts concerning growers' critical need for DCPA as a crop protection tool for which there are no actual, viable and/or economical alternatives are established in the factual testimony of Chris Valadez (PGX 6), and the expert testimony of Steven Fennimore (PGX 7A) and Richard Smith (PGX 8), as well as the accompanying exhibits (PGX 1-3). The Agency does not dispute any of the facts established by the Growers. To the contrary, the Agency accepts them but says they should be ignored as irrelevant:

> [W]e believe that under FIFRA Section 3(c)(2)(B) and EPA's existing stocks policy specifically concerning suspensions under that section that questions of market disruption or availability are not relevant to the context of whether or not a product should be suspended. EPA is not contesting the – that market effects may occur, but simply that they are not relevant to the scope of this hearing.

Tr. 385:23-386:5 (Dkt. 58). Thus, as discussed below, the record establishes that the existing stocks provision in the NOITS will have significantly adverse impacts on growers who rely on DCPA as an essential and irreplaceable crop protection tool. In turn, it also will impact American consumers, in the form of lesser availability and higher prices for the allium (*e.g.*, onion, green onion, leek, scallion, etc.) and brassica (*e.g.*, broccoli, cauliflower, radish, gai lon,

bok choy, kohlrabi, Brussels sprouts, cabbages) crops for which DCPA is a key and irreplaceable crop protection tool.

III. ARGUMENT

A. Legal Framework and EPA Policy for Existing Stocks

FIFRA § 3(c)(2)(B)(iv) authorizes the Administrator to include reasonable provisions concerning the disposition of its existing stocks of a 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 with regard to its determination of existing stocks, that discretion is not unbounded. Any provisions imposing limitations on existing stocks must be appropriate, rational and consistent with FIFRA. *Id.* In the analogous context concerning review of an agency's exercise of discretion under the Administrative Procedure Act, the Agency may not consider "factors which Congress has not intended it to consider, entirely fail[] to consider an important aspect of the problem or offer[] an explanation for its decision that runs counter to the evidence before the agency …." *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see Petroleum Communications, Inc. v. FCC*, 22 F.3d 1164, 1172 (D.C. Cir. 1994) ("Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, we must undo its action"); *Melcher v. FCC*, 134 F.3d 1143, 1152 (D.C. Cir. 1998) (agency action must be "supported by substantial evidence and based upon a consideration of the relevant factors, and … have a rational connection to the facts found").

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, suspended 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]").

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.* at 29362. 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. *Id.* 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 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* FIFRA § 6(c), 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* FIFRA §§ 4(d)(6), (f)(3), 7 U.S.C. §§ 136b(d)(6), 136b(f)(3). In the case of imminent hazard declarations, not implicated here, 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.

B. The Growers' Testimony and Evidence Concerning the Impact of the Existing Stocks Provision in the NOITS is Relevant to this Proceeding

1. FIFRA Expressly Authorizes Interested Persons Adversely Affected by a Suspension Notice to Obtain a Hearing

Under FIFRA, the Grower Group as "person[s] adversely affected by the [suspension] notice," has the express right to request a hearing to address, *inter alia*, "whether the Administrator's determination with respect to the disposition of existing stocks is consistent with [FIFRA]." FIFRA § 3(c)(2)(B)(iv), 7 U.S.C. § 136a(c)(2)(B)(iv); *see* JX 2 at 3. Thus, the plain terms of the statute authorize, and necessarily require, consideration of the impact of an existing stocks determination on a third party "adversely affected by" the NOITS. *Id.* Indeed, this matter illustrates why FIFRA § 3(c)(2)(B)(iv) permits not only the registrant, but also those adversely affected by a suspension, to request a hearing. If the impact of a suspension of a pesticide registration on those adversely affected by it were not an appropriate subject for the hearing, there would be no reason to provide that a non-registrant can request hearing on the terms of a suspension. Thus, the Agency's position that evidence of the impact of the existing stocks provision on the Grower Group is irrelevant to this proceeding violates the long-established canon of statutory interpretation that precludes interpreting a statute in a manner that would render its terms surplusage. *See Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant").

2. Under the Existing Stocks Policy, the Grower Group's Testimony is Relevant to Agency's Justification for the Existing Stock Provision

The Agency's reliance on alleged concerns of uncertain risk to justify the existing stocks provision for DCPA also makes the Grower Group's testimony and evidence relevant under the Agency's Existing Stocks Policy. *See* RX 27 at 8 ("In the case of the NOITS for DCPA, consideration of this uncertainty was the reason behind the existing stocks provisions the Agency put forward") (Bloom). Critically, except in situations involving imminent risk (which the Agency does not contend is present here), the Existing Stocks Policy does not permit the Agency to consider risks (or "uncertain risks") in isolation from the benefits of a registered pesticide. *See, e.g.*, 56 Fed. Reg. at 29364 (permitting distribution of existing stocks of a pesticide raising risk concerns whose registration has been cancelled if "social, economic, and environmental benefits associated with such distribution, sale, or use exceed the social economic, and environmental risks"); *see id.* at 29364, 29367 (identifying benefits to be considered, 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). Because the Agency seeks to rely on "uncertain" risks to justify the existing stocks provision for DCPA, it therefore necessarily must consider the benefits of the product. It must do so not only to comply with its published guidance in the Existing Stocks Policy, *id.*, but also to ensure compliance with the broader statutory mandate that any existing stocks policy issued under the Suspension Provision is "consistent with" FIFRA and not irrational. The Agency's concession that it failed to undertake this analysis raises the question of whether the existing stocks provision in the NOITS could survive rationality review, even if the narrow portion concerning formulation of existing stocks of technical DCPA in AMVAC's possession at the time of suspension is excised by the Presiding Officer.

3. The Undisputed Facts Concerning Growers' Critical Need for DCPA

As noted, the Agency does not dispute any of the evidence of the significant and adverse impacts that the existing stocks provision of NOITS will create by prohibiting AMVAC from formulating technical DCPA in its possession if the suspension goes into effect. When end use products containing DCPA are no longer available, growers will be deprived of a critical and irreplaceable tool. PAB 96 ¶¶ 10, 12 (Ranganath); Tr. 385:8-12 (Ranganath).

"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 7A ¶ 13 (Fennimore); *see* 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 such as bok choy, Brussels sprouts, broccoli, cauliflower, cabbages, radish, kale, rapini, mustards, collards, gai lon and kohlrabi); PGX 7A ¶ 15 (Fennimore) ("There are a limited number of herbicides that are registered for the same crops as DCPA … that have similar selectivity and efficacy"). In addition, brassica crops also are "critical components" of cropping systems that must be used to maintain soil health for the growth of other crops. PGX 7A ¶ 14 (Fennimore).

The essential importance of DCPA as an indispensable, foundational tool for its registered uses cannot be overstated. It serves as a critical, first level of preemergent control that greatly reduces or slows down weed growth, which makes second level post-emergent means of control work more effectively. *Id.* 8 ¶ 13 (Smith). It is used on crops that are grown year-round and therefore face the full range of pest pressures, weather events including unpredictable weather. PGX 7A ¶ 31-32 (Fennimore). This, in turn, increases the importance of early, effective weed control because weather events may reduce or eliminate the ability to enter the field during the growth cycle for application of post-emergent weed control. *Id.*; *see* PGX 6 ¶ 39

(Valadez) ("rainy wet fields are impossible to cultivate or hand weed, so weeds will grow and complete").

Should the existing stocks provision in the NOITS eliminate access to DCPA, there are no registered herbicides that could replace all its uses. PGX 7A at ¶ 16 (Fennimore); *see also id.* ¶¶ 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."). For example, it is the *only* registered herbicide that can be used for onions from the time of seedling to 1-2 leaf. PGX 7A ¶ 17; *see* PGX 8 ¶ 10 (Smith) (explaining complex challenges for weed control in onions caused by nature of onion growth).

Mechanical or hand weeding also cannot replace DCPA. PGX 6 ¶ 34 (Valadez); *see id.* ¶¶ 35-40 (explaining why mechanical and hand weeding are not available, viable and/or economical). Mechanical weeding of onions is not possible due to onion production systems. PGX 8 ¶ 11 (Smith); *see* 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"). Similarly, hand weeding "is neither a viable nor an economic option." PGX 6 ¶ 36 (Valadez). It is not a viable option because the availability of labor for hand weeding has decreased significantly and is uncertain at best. PGX 6 ¶ 37 (Valadez) ("growers cannot count on being able to obtain hand labor when it is needed. If it is not available when needed, the impact can be devastating and result in crop loss, decreased yields and increased prices to the American consumer."). Even if growers were able to secure labor for hand weeding, it would

significantly increase production costs which then would be passed to the American consumer. *See id.* ¶¶ 12-18, 40-42 (discussing costs and shortages of labor for hand weeding, and impact on prices). In short, "given the high cost and increasing shortages of labor, hand weeding [cannot] be relied upon as the solution should [DCPA] no longer be available." PGX 3 at 44 (citations omitted); PGX 6 ¶ 38 (Valadez) ("there is no reason to believe the labor market can provide a labor force for hand weeding that can substitute for DCPA…. Even if sufficient labor were available, it is a much more expensive solution that would lead to substantially higher costs.").

The impact of the loss of access to DCPA by growers who rely on it, in addition to the already "unprecedented challenges" they face, could be "catastrophic." PGX 6 ¶ 11 (Valadez). These challenges include: labor costs and shortages; increased costs for transportation, logistics, pallets and packaging; challenges posed by weather and climate issues; and increased costs for other crop protection inputs (seed, chemical, fuel). PGX 6 ¶ 11 (Valadez); *see id.* ¶¶ 12-32. "With higher costs and lower returns, growers and producers face downward pressure on production as fewer acres are planted and harvested, or existing fields are managed less intensively (resulting in lower yields). The elimination of DCPA would put significant upward pressure on prices." PGX 6 ¶ 41 (Valadez). "The American consumer also will incur the increased costs for crops that rely on DCPA directly, as well as increased costs for crops that are rotated with the crops treated with DCPA. The impact of these costs will be particularly acute given the already present impacts of inflation and rising input costs for growers and consumers." PGX 6 ¶ 42 (Valadez).

4. The Agency Failed to Weigh the Critical Needs and Benefits of DCPA Against Alleged "Uncertain Risks"

The Agency does not dispute any of these facts demonstrating the "catastrophic" impacts that may follow if growers lose access to DCPA under the existing stocks provision. Rather, it

contends only that they should be ignored. Thus, the record establishes that the Agency failed to consider the critical needs and benefits of DCPA and the impact the DCPA existing stocks provision would have, and, in fact, it deemed any such considerations irrelevant. The Agency repeatedly stated its position that consideration of the benefits of DCPA, including the lack of alternatives for its uses and the significant market disruptions and burden on growers that the existing stocks provision for DCPA will create, to be irrelevant. *See, e.g.*, EPA Pre-Hrg. Br. at 27 (Dkt. 48); Tr. 386:1-5 ("questions of market disruption or availability are not relevant to the context of whether or not a product should be suspended. EPA is not contesting the – that market effects may occur, but simply that they are not relevant to the scope of this hearing"). Because the Agency's existing stocks provision for DCPA is based on allegations of "uncertain risks" without weighing them against the benefits of DCPA, the Agency's determination is not consistent with the Existing Stocks Policy. *See, e.g.,* 56 Fed. Reg. at 29363.

Similarly, allowing EPA to use an existing stocks provision in the context of a suspension proceeding to remove a product from the market based on concern of "uncertain risks" is inconsistent with FIFRA. As discussed below, at most, the Agency sought to justify the existing stocks provision based on vague assertions of uncertainty in risk because a CTA study had not been submitted as of the date of the NOITS. However, when the Agency seeks to remove a product from the market based on risk, it cannot (mis)use other mechanisms under FIFRA that are not intended to address those concerns to order to avoid conducting a full cancellation hearing. *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 35 (D.D.C. 2011). To the extent the Agency seeks to vindicate concerns of risk under FIFRA, it must comply with the procedures required by the cancellation process. Permitting the Agency to shortcut or avoid the significant steps and processes applicable when it seeks to remove a product from the market based on risk

would be particularly inappropriate where, as here, the Agency's position is based on "uncertainty" (that the Agency concedes no longer exists, as noted below) rather than actual findings of risk.

C. The Record Does Not Support the Agency's Justification for the Existing Stocks Provision in the NOITS

Putting aside the Agency's failure to weigh its concerns of "uncertain risks" against the benefits of DCPA, evidence presented at the hearing also demonstrates that its risk-based justification also is without basis. In particular, Ms. Bloom explained that the existing stocks provision in the NOITS is "fully consistent with FIFRA's goals to protect humans and the environment from unreasonable adverse effects" because "the risk picture is so uncertain that EPA cannot even make conservative estimates." RX 27 at 8. However, evidence at the hearing demonstrated that at least up until the some undisclosed, fairly recent date, the Agency's position was that outstanding DCI data requirements did not prevent it from conducting risk assessments; rather, the Agency could – *and indicated it would* – conduct the assessments based on conservative estimates. *See, e.g.*, JX 21 at 1 ("A substantial portion of the data required in [DCI] has not yet been submitted and is outstanding. The Agency will rely upon data available at the time when the risk assessments are being developed.); JX 32 at 1 ("Where the Agency is lacking data, conservative assumptions may be used in their place to complete the risk assessments"); JX 65 at 25 ("in the absence of toxicity data for the degrade TPA, EFED will make highly conservative assumptions when evaluating the toxicity of TPA"); JX 79 at 2 ("In the absence of the anaerobic soil and aquatic metabolism studies for TPA, EFED" will make "conservative assumptions").

Certain of the Agency's testimony on this point was in accord:

> Q. Was it EFED's belief that it could not conduct a risk assessment at all, or only that it would be forced to make conservative assumptions if it were to do so?

A. Very conservative. Make conservative assumptions.

Tr. 62:19-23 (Wendel); *see also* Tr. 83:1-7 (confirming that "[w]here the agency is lacking data conservative assumptions may be used in their place to complete the risk assessments") (Wendel); Tr. 232:14-16 ("conservative assumptions would be made if [the Agency] didn't get the data and so we told AMVAC that was the case with many of these requirements") (Bloom). However, other testimony by the same witnesses reflected some variation, or equivocality, as well as a shift, in the Agency's position as to its ability to use conservative assumptions to complete risk assessments, at least with respect to the CTA study.[4] *See* Tr. 233: 15-19 (Bloom); Tr. 107:3-8 (Wente). This change occurred at some point in time prior to issuance of the NOITS in April 2022 (JX 1) but after the October 2020 "data delay letter" (JX 21). Specifically, in October 2020, EPA noted that "[a] substantial portion of the data required in the [DCI] is outstanding," that the "Agency will rely upon data available at the time when the risk assessments are being developed," and [w] here the Agency is lacking data, conservative assumptions may be used in their place to complete the risk assessments." JX 21 at 1. However, in the April 2022 NOIS the Agency informed AMVAC that "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 …." JX at 1. Notably, the NOITS was EPA's first communication to AMVAC that its position as reflected in the "data delay letter" (JX 21) had changed. Tr. 234:22-235:7 (Bloom). This lack of communication likely contributed to, if not

[4] According to Ms. Bloom, the CTA study is the only requirement for which the Agency determined it could not use conservative assumptions. Tr. 233:15-234:14 (Bloom); *see also* 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 …").

explains, the confusion reflected in Agency documents and testimony as to this issue.

Regardless of the timing and circumstances of both the Agency's change in position on the CTA study and when it communicated its change in position to AMVAC, the evidence establishes that AMVAC submitted the CTA study to EPA *months* ago, in June 2022. PAX 95 ¶¶ 143-149 (testimony concerning submission and supplementation of final CTA study) (Jonynas); Dkt. 34 at 2 (OPP considers DCI data requirement for CTA study to be satisfied). Indeed, at the hearing, the Agency objected to the relevance of testimony concerning the CTA study on the grounds that the Agency "consider[s] [the requirement] satisfied. Tr. 202:12-14. The Agency also confirmed that there are no unfulfilled data requirements for which it cannot use conservative assumptions. Tr. 242:15-18 ("[W]e're still missing some data that are important, but for those we'd probably make the conservative assumptions we talked about. So, we have all of the health information we need.") (Bloom). Accordingly, the proposition that the existing stocks provision in the NOITS is consistent with FIFRA because "the risk picture is so uncertain that EPA cannot even make conservative estimates" is belied by the facts adduced at the hearing. Because the Agency put forward "this uncertainty [as] *the* reason behind the existing stocks provisions" (RX 27 at 6-8 (Bloom)), and the record establishes that any such "uncertainty" has been resolved, the existing stocks provision is entirely unsupported by the record and cannot be sustained.

D. The Existing Stocks Provision is Irrational

Given that the sole justification the Agency offered for the existing stocks provision in the NOITS – the lack of a CTA study – no longer exists, the Agency's failure (or refusal) to reevaluate that provision is unreasonable and irrational. This is particularly true given that the Agency reevaluated and substantially narrowed the basis for the NOITS in which that provision is contained. *See, e.g.*, Dkts. 34, 43, 53 (indicating that the CTA data requirement has been

satisfied, and OPP will not seek suspension based on several other data requirements). Just as OPP has an obligation to reevaluate the data requirements for which it is seeking suspension as data is submitted, it also is obliged to reevaluate its existing stocks determination when the data it asserted was relevant to that provision (*i.e.*, the "uncertainty" due to lack of final CTA data)) has been submitted, and in fact was submitted to EPA almost a year ago.

But even if the CTA study had not been submitted (and the Agency had not concluded that the requirement for that study has been satisfied), the terms of the existing stocks provision make no sense and remain irrational. As noted, the Existing Stocks Policy requires a fact-specific analysis, and the only purported "fact" the Agency considered was "uncertain risks." 56 Fed. Reg. at 29362. In particular, the existing stocks provision allows for the continued sale, distribution and use of end-use products containing DCPA formulated prior to the effective date of the suspension order. It also allows the sale, distribution and use of end-use products containing DCPA formulated *after* the effective date of the suspension to the extent existing stocks of AMVAC's technical DCPA is in the hands of third parties. As such, assuming *arguendo* that the Agency established at the hearing that "uncertain risks" justify the existing stocks provision in the NOITS, the terms of that provision are irrational.

The existing stocks provision of the NOITS would permit a third party to formulate end use products from existing stocks of technical, but prohibits AMVAC from doing the same. It also permits continued sale and use of end use products containing DCPA following the suspension. However, the record provides no basis to conclude that there is a difference in "uncertain risk" if AMVAC is the formulator of the existing technical into end-use product rather than third party. Similarly, the record provides no support for the proposition that "uncertain risk" is present if AMVAC formulates technical DCPA into end use products following

suspension, but not if the formulated end use products are actually used. Indeed, it is difficult to conceive how the "uncertain risk" on which the Agency sought to justify a prohibition on AMVAC's formulation of technical into an end use product after the suspension vanishes when those end use product are actually applied on crops.

While the Growers acknowledge that the Agency has discretion in its determinations of existing stocks, such provisions must be appropriate, rational and consistent with FIFRA. 7 U.S.C. § 136a(c)(2)(B)(iv), FIFRA § 3(c)(2)(B)(iv). Because the terms and justification for the existing stocks provision in the NOITS are incongruous and cannot be harmonized in any rational way, the provision falls outside a reasonable exercise of the Agency's discretion. *Cf. Petroleum Communications, Inc.,* 22 F.3d at 1172 (an agency abuses its discretion under the APA when its action is unsupported by a reasoned explanation); *Melcher,* 134 F.3d at 1152 (agency cannot take action that lacks "a rational connection to the facts found").

IV. 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 find that the existing stocks policy in the NOITS is: (1) based on a justification unsupported by the facts; (2) inconsistent with FIFRA; (3) inconsistent with the Agency's Existing Stocks Policy; and (3) incoherent and irrational. As such, 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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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2023, the foregoing **Petitioner Grower Group's Post-Hearing Brief**, was submitted to the following in the manner indicated below.

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