UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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,	)	**Docket No. FIFRA-HQ-2022-0002**
Petitioners.	)	

RESPONDENT'S MOTION FOR ACCLERATED DECISION

Respondent, the United States Environmental Protection Agency ("EPA" or "the Agency"), hereby moves before the Presiding Officer that an accelerated decision be entered in this matter, pursuant to 40 C.F.R. § 164.91, finding:

(1) that there is no genuine issue of material fact regarding Petitioner's, AMVAC Chemical Corporation ("AMVAC"), failure to take appropriate steps, within the time required by EPA, to secure the data required by the Data Call-In ("DCI") at issue in the Notice of Intent to Suspend ("NOITS") Petitioner's registered pesticide product, Technical Chlorthal Dimethyl (EPA Registration Number 5481-495), containing the active ingredient dimethyl tetrachloroterephthalate ("DCPA"), and that, as a matter of law, Petitioner's DCPA registration must be suspended until Petitioner has satisfied the Agency that Petitioner has complied fully with the requirements of the DCI; and

(2) that there is no material issue with respect to existing stocks of the product Technical Chlorthal Dimethyl (EPA Reg. No. 5481-495) and that, as a matter of law,

Respondent's determinations as to existing stocks are consistent with the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*, and its implementing regulations at 40 C.F.R. Subchapter E.

A Memorandum in Support of Respondent's Motion for Accelerated Decision is being filed with this motion.

Respectfully submitted,

FORREST PITTMAN

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87 Fed. Reg. 25262, Notice of Intent To Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration (Apr. 28, 2022).

I. SUMMARY OF THE ARGUMENT

Respondent, the Office of Chemical Safety and Pollution Prevention[1] of the United States Environmental Protection Agency ("EPA," or "the Agency"), submits this memorandum in support of its Motion for Accelerated Decision. Pursuant to 40 C.F.R. § 164.91, EPA asks the Presiding Officer to issue an order suspending the registration for the pesticide product Technical Chlorthal Dimethyl (EPA Registration Number 5481-495), containing the active ingredient dimethyl tetrachloroterephthalate ("DCPA"), issued to Petitioner, AMVAC Chemical Corporation ("AMVAC"), pursuant to Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq.*, due to AMVAC's failure to take appropriate steps to secure the data within the timeframes required by the January 31, 2013 Generic Data Call-In Notice ("DCI") (GDCI-078701-1140), as described in the Notice of Intent to Suspend ("NOITS") sent to AMVAC on April 27, 2022, and published in the Federal Register on April 28, 2022. 87 Fed. Reg. 25262, Petitioner AMVAC Exhibit ("PAX") 2.

The only determination that the Presiding Officer must make prior to suspending AMVAC's product is whether AMVAC took appropriate steps to secure the data required by the DCI within the time required; EPA has clearly established that AMVAC failed to do so. There is no dispute that AMVAC failed to take the action specified in the DCI, to wit: submitting or citing data required for EPA to complete its registration review of the pesticide active ingredient DCPA by specified deadlines. 87 Fed. Reg. 25262, PAX 2. The relevant factual basis supporting EPA's request for accelerated judgment is, as a matter of law, partially uncontested by AMVAC.

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[1] In this matter, the Administrator of the EPA has designated the Assistant Administrator of the Office of Chemical Safety and Pollution Prevention ("OCSPP") as an EPA employee who does not have a connection to the case and, accordingly, is available to advise the Administrator in the instance this matter is ultimately appealed to the Administrator pursuant to 40 C.F.R. § 164.2(g). In compliance with the prohibitions on *ex parte* communications found in 40 C.F.R. § 164.7, the OCSPP Assistant Administrator's FIFRA authorities as to this specific case are delegated to the Deputy Assistant Administrator for Pesticide Programs.

With respect to at least 3 of the 20 outstanding data requirements, AMVAC concedes the factual basis required to suspend the registration at issue in this matter; each of these AMVAC failures to submit the required data is independently sufficient to support suspension. *See infra* sections III.B.6, III.B.7, and III.B.20 (AMVAC acknowledges that the data requirements remain outstanding and that it would "initiate work to fulfill the . . . requirement[s] for DCPA").

Twenty data requirements specified in the DCI remain unsatisfied, either due to AMVAC's failure to submit data years after the deadline for submission and in some cases years after informing EPA of its intent to comply with the DCI, or to AMVAC's submission of repetitive requests that EPA waive the DCI data requirements after EPA previously denied similar waiver requests.

EPA also asks that the Presiding Officer determine that the provisions in the NOITS as to existing stocks of AMVAC's suspended DCPA product are consistent with FIFRA and its implementing regulations at 40 C.F.R. Subchapter E. FIFRA explicitly provides EPA with broad discretion when considering whether to allow the continued sale and use of existing stocks in connection with the suspension of pesticide registrations for failure to submit data in response to a DCI. *Cf.* 7 U.S.C. § 136a(c)(2)(B); 56 Fed. Reg. 29362, 29367. Pursuant to longstanding policy, EPA will "generally not allow the registrant to sell or distribute any existing stocks during the pendency of the suspension." 56 Fed. Reg. 29362, 29367. The existing stocks determinations in the instant NOITS are consistent with EPA's historical and recent practice. *See, e.g.*, 80 Fed. Reg. 11669, 11671 (notifying affected registrants that, should the suspension become effective, registrants may not legally "distribute, sell, use, etc." the affected products); 79 Fed. Reg. 49308, 49310 (notifying the affected registrant of the same existing stocks provisions as described above).

Under FIFRA Section 3(c)(2)(B)(iv), "the only matters for resolution [] shall be whether [AMVAC] has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's[2] determination with respect to the disposition of existing stocks is consistent with [FIFRA]." 7 U.S.C. § 136a(c)(2)(B)(iv). Any attempt on the part of AMVAC or other Petitioners to broaden this hearing to include other matters, such as the technical sufficiency of its data submissions and waiver requests, or EPA's rationale for requiring the submission of certain data, are barred by law. 7 U.S.C. § 136a(c)(2)(B)(iv).

Accordingly, EPA asks the Presiding Officer to issue an accelerated decision (1) suspending AMVAC's DCPA pesticide registration (EPA Reg. No. 5481-495) as a result of AMVAC's failure to comply fully with the data requirements of the data call-in GDCI-078701-1140, and (2) upholding the existing stocks determinations contained in EPA's April 28, 2022 Notice of Intent to Suspend.

II. LEGAL BACKGROUND

A. The Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA provides for Federal regulation of pesticide distribution, sale, and use. 7 U.S.C. § 136, *et seq.* Generally speaking, all pesticides distributed or sold in the United States must be registered (*i.e.*, licensed) by EPA. *Id.* § 136a(a). Before EPA may register a pesticide under FIFRA, an applicant must show, among other things, that using the pesticide according to its specifications "will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(D). FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic,

[2] References to the EPA Administrator's authorities in this memorandum use the generic terms "EPA" or "Agency."

social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section [408 of the Federal Food, Drug, and Cosmetic Act ("FFDCA")]. . . ." *Id.* § 136(bb) (citing 21 U.S.C. § 346a).

B. FIFRA Section 3(g); Registration Review

EPA must periodically review pesticide registrations. 7 U.S.C. § 136a(g); 40 C.F.R. § 155.40 *et seq*. This "registration review" results in EPA making a "determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA." 40 C.F.R. § 155.57. In the registration review process, EPA creates a "registration review case" for one or more active ingredients in a pesticide and all products containing such ingredients, establishes a docket for public participation, and provides an opportunity for comment. *Id.* §§ 155.42, 155.50. Part of the registration review process is to identify risks of concern and to implement actions that can mitigate these risks. 40 C.F.R. §§ 155.53, 155.56. During registration review of a pesticide, EPA must "consider whether to conduct a new risk assessment to take into account, among other things, any changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements [and] any new data or information on the pesticide." *Id.* § 155.53(a). Where EPA finds that a new assessment of the pesticide is needed, "it will determine whether it can base the new assessment on available data or information." *Id.* § 155.53(b)(1). "If sufficient data or information are available, the Agency will conduct the new risk assessment or risk/benefit assessment" based on such existing information. *Id.*

C. FIFRA Section 3(c)(2)(B); Data Call-Ins

Throughout the life of a pesticide's registration and commonly when EPA is reevaluating a pesticide for registration review, "[i]f the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under

FIFRA section 3(c)(2)(B)." *Id.* EPA "may issue a Data Call–In notice under FIFRA Section 3(c)(2)(B) at any time if the Agency believes that the data are needed to conduct the registration review." 40 C.F.R. § 155.48; *see* 7 U.S.C. §§ 136a(c)(2)(B), 136a(g)(2). If EPA determines that a DCI is required for registration review, it "shall notify all existing registrants of the pesticide to which the determination relates," and "shall permit sufficient time for applicants to obtain" the data required to be submitted. 7 U.S.C. §§ 136a(c)(2)(B), 136a(c)(2)(A). EPA acknowledges that issuance of a DCI places a burden on pesticide registrants and, accordingly, provides notice of data required for the Agency to complete registration review and an opportunity for registrants and others to comment on proposed data requirements. *See* DCPA Registration Review Docket, EPA-HQ-OPP-2011-0374-0002. EPA typically receives comments from registrants and other interested stakeholders concerning anticipated data requirements. *See, e.g.,* Cyflufenamid Registration Review Docket, EPA-HQ-OPP-2021-0733 (comments both from registrant contesting need for potential DCI requirements and from third party claiming that additional data is required for EPA to make a determination under FIFRA). Additionally, prior to issuing a DCI, EPA requests approval from the United States Office of Management and Budget before requiring registrants to submit the data required for registration review to ensure compliance with the Paperwork Reduction Act.[3]

[3] Under OMB's approval of EPA DCIs for registration review, the following requirements apply:
DCIs must be approved by high-level management (Deputy Division Director or above). Before EPA may issue a specific DCI under this approval, EPA must provide OMB with prior notice and opportunity to review the DCI. The information sent to OMB shall include basic information on the pesticide, the total number of respondents, the planned schedule for issuance and data submission, a list of required studies, the practical utility of the data, and an estimate of the paperwork burden and testing costs. OMB may request that EPA provide additional information as necessary to explain the basis for the DCI. OMB expects review of specific planned DCIs will be prompt (15 working days after OMB confirms receipt), although OMB will notify EPA if there are issues that require additional time for review. OMB may also request that EPA issue a FR notice seeking public comment on the DCI. Based on its review, OMB may determine that any one or more requested DCIs do not comply with the requirements in 5 CFR 1320.5(d) and return the

It is important to note that while EPA promulgated regulations in 40 C.F.R. Part 158 outlining the kinds of data routinely required to make regulatory judgements under FIFRA about the risks and benefits of a pesticide product, the Agency retains maximum flexibility to require other types of data. *See* 40 C.F.R. § 158.75. Pursuant to 40 C.F.R. § 158.30:

> EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. . . . [T]he data routinely required in [40 C.F.R. Part 158] may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects to man or the environment. EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.

Similarly, pursuant to 40 C.F.R. § 158.45, registrants may request that EPA waive certain data requirements by showing that the data, for instance, would not be appropriate for the product at issue. Some justifications for waiver of a data requirement include that:

> Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product.

Id. § 158.45(a). "The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards." *Id.* EPA must inform the registrant in writing of its decision to grant or deny a data waiver request. *Id.* § 158.45(c).

> request to EPA for reconsideration. In such cases, EPA may not issue the DCI(s) before addressing the issues raised and resubmitting the request.

Office of Management and Budget, Pesticides Data Call-In Program, OMB Control No. 2070-0174, ICR Ref. No. 200809-2070-002, available at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200809-2070-002.

D. FIFRA Section 3(c)(2)(B)(iv); Suspension

If EPA "determines that a registrant, within the time required by the [Agency], has failed to take appropriate steps to secure the data required . . ., the [Agency] may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required." 7 U.S.C. § 136a(c)(2)(B)(iv).[4] The suspension of a registration proposed in a notice of intent to suspend

> shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied [EPA] that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend.

Id.

E. FIFRA Section 6(d) and 40 C.F.R. Part 164; Hearing

Under FIFRA Section 3(c)(2)(B)(iv), "[i]f a hearing is requested, a hearing shall be conducted under [FIFRA Section 6(d)]." *Id.* Regulations pertaining to hearings arising under FIFRA Section 6(d) are conducted pursuant to the rules of practice at 40 C.F.R. Part 164. Hearings concerning suspension of a registration for failure to comply with a DCI are governed by 40 C.F.R. Part 164, subpart B.[5] "If a hearing is held [under FIFRA Section 3(c)(2)(B)(iv)], a decision after completion of such hearing shall be final." *Id.* § 136a(c)(2)(B)(iv). Any registration suspended, either with or without a hearing, for failure to comply with a DCI, shall only be reinstated if EPA determines that the registrant has complied fully with the DCI. *Id*.

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[4] FIFRA Section 3(c)(2)(B) also provides for registrants to agree to jointly develop data responsive to a DCI or to share in the cost of developing that data, and, if necessary, for EPA to enforce such agreements with a notice of intent to suspend. 7 U.S.C. § 136a(c)(2)(B). In the instant case, AMVAC is the only registrant of pesticide products containing DCPA and, accordingly, the provisions of FIFRA Section 3(c)(2)(B) concerning such agreements are not germane.

[5] While 40 C.F.R. § 164.3 provides that "suspension hearings" are governed by subpart C, the text of subpart C make clear that it applies not to data-submission suspensions hearings under FIFRA Section 3(c)(2)(B)(iv), but rather to expedited suspensions under FIFRA Section 6(c). *Cf.* 40 C.F.R. § 164.120; 7 U.S.C. 136d(c). The provisions of 40 C.F.R. Part 164, subpart B, apply to proceedings "other than expedited hearings."

EPA's broad authority to determine whether a registrant has complied with the terms of the DCI is unambiguously stated in the text of FIFRA Section 3(c)(2)(B)(iv). *Id.*; *see also Chevron U.S.A. v. NRDC*, 467 U.S. 837, 842-43 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

It is important to note that the scope of issues that may be addressed in a hearing are tightly constrained by FIFRA Section 3(c)(2)(B)(iv). *Id.* § 136a(c)(2)(B)(iv). "The only matters for resolution at that hearing shall be:"

(1) "whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide" (*i.e.*, whether the registrant submitted the data required by the DCI); and
(2) "whether [EPA's] determination with respect to the disposition of existing stocks is consistent with [FIFRA]."

Id. "This strict limitation on the scope of a [] proceeding precludes a registrant from collaterally attacking" other matters. *In re: Bayer Cropscience LP and Nichino America, Inc.*, 17 E.A.D. 228, FIFRA-HQ-2016-0001, 2016 WL 4125892 at 5 (EAB 2016) (interpreting a similar restriction on the scope of hearings conducted pursuant to FIFRA Section 6(e)). Exceptions and interpretations of FIFRA Section 3(c)(2)(B)(iv) not supported by the clear language of the statute, such as extensions to the effective date of the suspension, are not appropriate. *In re: TIFA Ltd.*, 9 E.A.D. 145 at 6, FIFRA Appeal No. 99-5, 2000 WL 739401 (EAB 2000) (reversing ALJ's extra-statutory interpretations of FIFRA Section 3(c)(2)(B)(iv)).

Similarly important, FIFRA Section 3(c)(2)(B)(iv) sets a short period for resolution of a registrant's challenge to an EPA notice of intent to suspend. *Id.* "[A] hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing." *Id.*

F. FIFRA Section 6(a)(1); Existing Stocks

FIFRA Section 12(a)(1)(A) makes it an unlawful act for a person to distribute or sell to any person a pesticide that has been suspended. 7 U.S.C. § 136j(a)(1)(A). In the case of suspension of pesticide registrations for failure to comply with a DCI, FIFRA Sections 6(a)(1) and 3(c)(2)(B) explicitly provide EPA with broad discretion to allow sale or use of existing stocks, if consistent with FIFRA. 7 U.S.C. §§ 136d(a)(1), 136a(c)(2)(B).[6] In a notice of intent to suspend issued under FIFRA Section 3(c)(2)(B)(iv), EPA "may include in the notice of intent to suspend such provisions as the [Agency] deems appropriate concerning the continued sale and use of existing stocks of such pesticide." *Id.* § 136a(c)(2)(B)(iv). Under FIFRA Section 6(a)(1), EPA "may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended [] under [FIFRA Section 3], to such extent, under such conditions, and for such uses as [EPA] determines that such sale or use is not inconsistent with the purposes of [FIFRA]." *Id.* § 136d(a). In 1991, EPA outlined the policies that generally guide the Agency in making individual decisions concerning whether, and under what conditions, the Agency will permit the continued sale, distribution, and use of existing stocks of pesticide products whose registrations are amended, cancelled, or suspended. 56 Fed. Reg. 29362 (Jun. 26, 1991). "Where a pesticide is suspended because of failure to comply with the provisions of a data call-in [], the Agency will generally not allow the registrant to sell or distribute any existing stocks during the pendency of the suspension." *Id.* at 29367. "[T]he Agency does not anticipate generally placing restrictions on the sale, distribution, or use of existing stocks by persons other than the registrant where a pesticide is suspended because of failure to comply with the provisions of a data call-in or reregistration requirement unless risk concerns were identified." *Id.*

[6] FIFRA Section 6(a)(1) uses slightly different language, "such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of [FIFRA]."

III. FACTUAL BACKGROUND

A. Dimethyl Tetrachloroterephthalate

DCPA is a chlorinated benzoic acid or phthalate pre-emergence herbicide. It is registered for use on a variety of agricultural and non-agricultural sites, including corn, soybean, cole crops, cucurbits, peppers, herbs, and non-residential turf and ornamentals. EPA-HQ-OPP-2011-0374-0008. DCPA is used to control annual grasses and certain annual broadleaf weeds. It was first registered in the U.S. in 1958. *Id.* AMVAC is the only current registrant of pesticide products containing DCPA. The primary environmental degradation product[7] of DCPA is tetrachlorophthalic acid ("TPA").

B. DCPA Registration Review and 2013 Data Call-In

On June 29, 2011, EPA initiated registration review of the active ingredient DCPA. EPA-HQ-OPP-2011-0374-001, 76 Fed. Reg. 38166 (Jun. 29, 2011). As a result of its initial evaluation, the Agency determined that additional data on DCPA and TPA were necessary for EPA to complete registration review and for AMVAC to maintain the continued registration of its DCPA product (EPA Reg. No. 5481-495). PAX 4, EPA-HQ-OPP-2011-0374-0009. In the preliminary work plan for registration review, EPA described the additional data it believed were necessary to make a decision concerning continued registration of DCPA pesticide products. EPA-HQ-OPP-2011-0374-002. EPA provided a 60-day public comment period and invited comment on all aspects of the registration review plan, including proposed data submission

[7] EPA frequently requires submission of data concerning the environmental fate, biotic degradation, and toxicology of the naturally occurring degradation products of a pesticide active ingredient, to facilitate understanding of the risks associated with the use of the pesticide. In many cases, the biotic and abiotic degradation of a pesticide into its degradates and metabolites (the terms may be used interchangeably) in the environment or in living systems are relevant to understanding those risks. Degradates may be toxic and may represent a large part of the overall exposures attributable to use of the pesticide, depending on their predominance after the pesticide is applied. *See* 40 C.F.R. § 158.130(d)(6). The degradation of DCPA results in the formation of a number of degradates, most significantly TPA. In addition to requiring data on the active ingredient DCPA, GDCI-078701-1140 specifically required submission of certain environmental fate and toxicological data for TPA.

needs. *Id.* Neither AMVAC nor any other entity submitted comments. EPA-HQ-OPP-2011-0374-0008.

Accordingly, on January 31, 2013, EPA issued a Generic Data Call-In Notice (GDCI-078701-1140 requiring AMVAC[8] to submit a number of studies. EPA-HQ-OPP-2011-0374-0009, PAX 4. The DCI listed only AMVAC's registration for the technical-grade DCPA product, EPA Reg. No. 5481-495 in Attachment 2.[9] *Id.* The DCI did not concern AMVAC's registered DCPA end-use products directly. The required data were due to EPA by various dates, the latest of which was 36 months after AMVAC's receipt of the DCI, specifically, January 31, 2016. *Id.*

Following years of communication concerning the data requirements of the DCI, as outlined in relevant detail below, in an October 16, 2020 letter ("Data Delay Letter"), EPA provided AMVAC with a detailed list of 21 still-outstanding data requirements. EPA-HQ-OPP-2011-0374-0013, PAX 21. Of the 21 outstanding requirements, 18 resulted from data waiver requests that had been previously denied, while the remaining 3 resulted from AMVAC's failure to submit data where AMVAC had not requested waiver of the requirement. *Id.* The letter also specified that EPA was currently reviewing 19 other data submissions from AMVAC, the acceptability of which had not been determined. *Id.* Following the Data Delay Letter, AMVAC satisfied 20 of the 40 outstanding DCI requirements by either providing acceptable data or through EPA waiving the requirement.

Each item of still-outstanding data is discussed below, with a reference to the relevant EPA Office of Chemical Safety and Pollution Prevention ("OCSPP") Final Test Guideline for

[8] AMVAC is the only registrant of pesticide products containing DCPA; accordingly, no other registrants were subject to the DCI.

[9] Technical-grade products are high-concentration forms of pesticides that are used to formulate into end-use pesticide products.

Pesticides and Toxic Substances Number, a brief description of the outstanding data required, whether the required data applies to DCPA or its degradate TPA as the test material, a brief summary of AMVAC's submissions to EPA and EPA's responses, and the current status of the data requirement. In summary, 20 data requirements still remain outstanding, including data needed for the assessment of DCPA's environmental fate, ecological toxicity, and human health risks.

The following data were required via the DCI for EPA to conduct the ecological and human health risk assessments during registration review of DCPA, as described in section II.B of this memorandum, above, and remain unsatisfied.

1. Guideline No. 835.4200, Anaerobic soil metabolism, TPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.1300, as explained in further detail in Guideline No. 835.4200, by January 31, 2015. EPA required a study of the anaerobic degradation of TPA in soil. Without this data, EPA's ability to characterize the anaerobic metabolism of TPA is limited. Such characterization would improve confidence in the Agency's understanding of the fate of DCPA and TPA in the environment. EPA-HQ-OPP-2011-0374-0014.

On April 29, 2013, AMVAC cited an existing study, EPA Master Record Identification number ("MRID") 114651, in support of this data requirement. PAX 5 at 20-21. On February 7, 2017, EPA classified MRID 114651 as supplemental[10] and required the submission or citation of additional data to satisfy this requirement of the DCI. EPA-HQ-OPP-2011-0374-0051, PAX 77.

[10] Pursuant to 40 C.F.R. § 158.70, EPA "will determine whether the data submitted or cited to fulfill the data requirements specified in this part are acceptable." Supplemental studies are at least partially useful for risk assessments, but have some deficiencies. Respondent's Exhibit 3, EPA Electronic Document Management Policy Update (Nov. 6, 2017). For example, a study may be classified as supplemental where it provides acceptable data for some species subject to a given data requirement and guideline, but is unacceptable for remaining species subject to that data requirement or guideline. *Id.*

After receiving no response from AMVAC, EPA notified AMVAC in the October 16, 2020 Data Delay Letter that this DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. On December 17, 2020, AMVAC submitted a data waiver request, arguing that compounds similar to TPA are initially stable in anaerobic environments but do degrade after a lag period and that, because "TPA is relatively innocuous to mammalian and aquatic life," no data responsive to Guideline No. 835.4200 are necessary for EPA to complete registration review of DCPA. MRID 51398102. On April 27, 2022, EPA denied AMVAC's data waiver request, noting that an anaerobic soil metabolism test of sufficient duration to derive a reliable anaerobic soil half-life for TPA degradation was needed to satisfy the data requirement. EPA-HQ-OPP-2011-0374-0014. While the guidance for developing anaerobic soil metabolism data indicates that test duration typically should not exceed 120 days, it allows that a study of longer duration may be needed to characterize the decline of the test substance and formation and decline of major transformation products. The Agency does not have sufficient information on the toxicity of TPA to conclude that it is "innocuous" in the environment. This data requirement remains outstanding.

2. Guideline No. 835.4300, Aerobic aquatic metabolism, TPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.1300, as explained in further detail in Guideline No. 835.4300, by January 31, 2015. EPA required a study of the aerobic metabolism of TPA in aquatic environments. Without this data, EPA cannot reliably estimate TPA's half-life in water, which will result in reduced confidence in the Agency's ecological risk and drinking water exposure assessment conclusions. EPA-HQ-OPP-2011-0374-0014. The data are particularly important in light of potential sensitivity in the developing thyroid, since any conclusions about thyroid toxicity have ramifications for the

DCPA drinking water risk assessment, especially for pregnant women and children. *See infra* section III.B.20.

DCPA, and especially its acid metabolites (including TPA), have been widely detected in groundwater surveys.[11] They are found in drinking water from public water systems sourced from groundwater, wells for community water systems, and private wells in many states. In some national surveys, DCPA acid metabolites were the most commonly detected chemicals altogether, and in 1991, the National Pesticide Survey reported a correlation between DCPA application rates in urban areas and golf courses and detections of DCPA acid metabolites. Registrant-sponsored prospective (controlled) groundwater monitoring studies documented the leaching of DCPA and its two acid metabolites into groundwater.[12] AMVAC and the Agency agree that TPA is persistent in water; the objective of the required study is to quantify that persistence by establishing definitive half-lives that can be used to derive expected environmental concentrations of TPA in water.

On April 29, 2013, AMVAC submitted a data waiver request, arguing that it would prefer to defer completing this study for TPA until similar data for DCPA was generated. MRID 49115401, PAX 5 at 21. AMVAC also proposed that EPA assess the risks from TPA using DCPA data. *Id.* On March 21, 2014, EPA denied AMVAC's data waiver request, noting that TPA is a major degradate of DCPA, that DCPA has up to a 100% conversion rate to TPA in the environment, and that the required data are critical to understand the degradation pathway of DCPA. EPA-HQ-OPP-2011-0374-0049, PAX 66. After receiving no response from AMVAC,

[11] National Pesticide Survey, U.S. Environmental Protection Agency (Fall 1990), *available at* *https://nepis.epa.gov/Exe/ZyPDF.cgi/10003H1X.PDF?Dockey=10003H1X.PDF*.

[12] DCPA Reregistration Eligibility Decision, U.S. Environmental Protection Agency (Nov. 1998) *available at* https://archive.epa.gov/pesticides/reregistration/web/pdf/0270red.pdf.

EPA notified AMVAC in the October 16, 2020 Data Delay Letter that this DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. On December 17, 2020, AMVAC briefly disputed EPA's reasons for denying the data waiver request but did not submit the required data or provide any new or additional evidence supporting its data waiver request. PAX 22. EPA did not consider AMVAC's contestation of the waiver request denial to constitute a second waiver request. This data requirement remains outstanding.

3. Guideline No. 835.4400, Anaerobic aquatic metabolism, TPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.1300, as explained in further detail in Guideline No. 835.4400, by January 31, 2015. EPA required a study of the anaerobic degradation of TPA in aquatic environments. Without these data, EPA's ability to characterize the anaerobic metabolism of TPA is limited. Such characterization would improve confidence in the Agency's understanding of the fate of DCPA and TPA in the environment. EPA-HQ-OPP-2011-0374-0014.

On April 29, 2013, AMVAC submitted a data waiver request arguing that EPA could estimate anaerobic aquatic metabolism at two times anaerobic soil metabolism half-life. MRID 49115401, PAX 5 at 25-26. On March 21, 2014, EPA denied AMVAC's data waiver request, noting that TPA is a major degradate of DCPA, that DCPA has up to a 100% conversion rate to TPA in the environment, and that the required data are critical to understand the degradation pathway of TPA. EPA-HQ-OPP-2011-0374-0049, PAX 66. Due to an administrative oversight, AMVAC did not receive notice of EPA's denial of the waiver until March 17, 2017. On February 22, 2018, AMVAC requested that EPA reconsider its data waiver request after the Agency reviewed data from studies of DCPA metabolism in soil either previously submitted or planned to be submitted in response to other DCI requirements. MRID 50533512. In the October

16, 2020 Data Delay Letter, EPA notified AMVAC that the waiver request was still denied and that this DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. On December 17, 2020, AMVAC submitted another data waiver request, arguing that TPA is stable until DCPA has been used in a given area over a period of several years, as populations of microorganisms capable of breaking down TPA would be likely to increase after repeated exposure. MRID 51398102, PAX 22. On April 27, 2022, EPA denied AMVAC's second data waiver request, noting that an anaerobic aquatic metabolism study of longer-than-standard duration is required to quantify a half-life of TPA in aquatic environments. EPA-HQ-OPP-2011-0374-0014. This data requirement remains outstanding.

4. Guideline No. 850.1350, Aquatic invertebrate life-cycle, estuarine/marine mysid, DCPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.630, as explained in further detail in Guideline No. 850.1350, by January 31, 2014. EPA required this study of DCPA's life-cycle toxicity to estuarine/marine invertebrates to overcome technical deficiencies in existing studies on DCPA chronic toxicity. Some existing studies suggest DCPA is much more toxic than TPA to aquatic invertebrates, although most of those studies had technical deficiencies (*e.g.*, testing performed above solubility limits with resulting uncertainty as to actual exposure concentrations). Without these data, the Agency is unable to assess risks for organisms of this type specifically and would likely have to extrapolate from data for other species or related compounds (surrogate data) if they are available, resulting in reduced confidence in the Agency's registration review ecological risk assessment overall. EPA-HQ-OPP-2011-0374-0055, PAX 59.

On January 29, 2014, AMVAC submitted data in response to this data requirement. MRID 49307512, PAX 27. In the October 16, 2020 Data Delay Letter, EPA notified AMVAC that the submitted data were being reviewed. EPA-HQ-OPP-2011-0374-0013, PAX 21.

On April 27, 2022, EPA informed AMVAC that the submitted data were classified as supplemental and could only be used for risk characterization, because a definitive no-observed-adverse-effect-concentration could not be established by the submitted study. EPA-HQ-2011-0374-0022. This data requirement remains outstanding.

5. Guideline No. 850.1350, Aquatic invertebrate life-cycle, estuarine/marine mysid, TPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.630, as explained in further detail in Guideline No. 850.1350, by January 31, 2014. EPA required this study of TPA's life-cycle toxicity for estuarine/marine invertebrates. The data are critical because of TPA's potentially high concentrations in the water column. EPA-HQ-OPP-2011-0374-0038; *see supra* section III.B.3. Without these data, the Agency is further hampered in assessing risks for organisms of this type, resulting in reduced confidence in the registration review ecological risk assessment overall.

On April 29, 2013, AMVAC submitted a data waiver request for this requirement. MRID 49115401, PAX 5 at 24. On March 21, 2014, EPA denied AMVAC's data waiver request. EPA-HQ-OPP-2011-0374-0038. In the October 16, 2020 Data Delay Letter, EPA notified AMVAC that this DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. On December 17, 2020, AMVAC submitted another data waiver request for this requirement, using the same argument as in its first request but citing studies performed on a different species (*Daphnia magna*, a freshwater invertebrate; mysids are estuarine-marine invertebrates). MRID 51398103, PAX 22.

On April 27, 2022, EPA denied AMVAC's second data waiver request, providing additional explanation for the denial. EPA-HQ-OPP-2011-0374-0038. This data requirement remains outstanding.

6. Guideline No. 850.1400, Fish early life-stage (freshwater fish: bluegill sunfish), DCPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.630, as explained in further detail in Guideline No. 850.1400, by January 31, 2014. EPA required a study of DCPA's toxicity to freshwater fish (warmwater species) in early lifestages. Without these data, the Agency is unable to assess risks for organisms of this type specifically and would likely have to extrapolate from surrogate data if they are available, resulting in reduced confidence in the registration review ecological risk assessment overall.

On April 29, 2013, AMVAC informed EPA that it intended to submit already-existing DCPA data for this DCI requirement, but never did so. EPA-HQ-OPP-2011-0374-0049, PAX 66; PAX 5 at 18-19. In the October 16, 2020 Data Delay Letter, EPA notified AMVAC that this DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. In a December 17, 2020 letter, AMVAC stated that would "initiate work to fulfill the . . . requirement for DCPA in early 2021." PAX 22. AMVAC indicated that this study was initiated in March 2021, and that a final report on the study would be submitted by June 15, 2022. Request for Hearing at 54. AMVAC submitted data for this requirement using a different species, fathead minnow, on June 7, 2022, which is currently being reviewed by EPA.

7. Guideline No. 850.1400, Fish early life-stage (estuarine/marine fish: sheepshead minnow), DCPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.630, as explained in further detail in Guideline No. 850.1400, by January 31, 2014. EPA required a study

of DCPA's toxicity to estuarine/marine fish in early lifestages. Without these data, the Agency is unable to assess risks for these organisms specifically and would likely have to extrapolate from surrogate data if they are available, resulting in reduced confidence in the registration review ecological risk assessment overall.

On April 29, 2013, AMVAC informed EPA that it intended to submit already-existing DCPA data for this DCI requirement, but never did so. EPA-HQ-OPP-2011-0374-0049, PAX 66; PAX 5 at 18-19. In the October 16, 2020 Data Delay Letter, EPA notified AMVAC that this DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. In a December 17, 2020 letter, AMVAC stated that would "initiate work to fulfill the . . . requirement for DCPA in early 2021." PAX 22. AMVAC indicated that this study was initiated in March 2021, and that a final report on the study would be submitted by July 15, 2022. Request for Hearing at 54. To-date, AMVAC has not submitted data for this requirement, which remains outstanding.

8. Guideline No. 850.1400, Fish early life-stage (freshwater fish: rainbow trout), TPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.630, as explained in further detail in Guideline No. 850.1400, by January 31, 2014. EPA required a study of TPA's toxicity to freshwater fish (coldwater species) in early lifestages. The data are critical because of TPA's potentially high concentrations in the water column, as explained above in section III.B.5 of this memorandum. EPA-HQ-OPP-2011-0374-0038. Without these data, the Agency is not able to assess risks to these organisms specifically and would likely have to extrapolate from surrogate data if they are available, resulting in reduced confidence in the registration review ecological risk assessment overall.

On April 29, 2013, AMVAC submitted a data waiver request for this data requirement, proposing that EPA wait until submission of the same study on DCPA and for the Agency to conduct its assessment using the toxicity endpoints determined for DCPA. MRID 49115401, PAX 5 at 23-24. On March 21, 2014, EPA denied the data waiver request. EPA-HQ-OPP-2011-0374-0049, PAX 66. In the October 16, 2020 Data Delay Letter, EPA notified AMVAC that this DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. On December 17, 2020, AMVAC submitted a second data waiver request for this requirement. MRID 51398103, PAX 22. On April 27, 2022, EPA denied the second waiver request. This data requirement remains outstanding.

9. Guideline No. 850.1400, Fish early life-stage (bluegill sunfish), TPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.630, as explained in further detail in Guideline No. 850.1400, by January 31, 2014. EPA required a study of TPA's early life-stage toxicity to freshwater fish species (warmwater species), due in part to potentially high concentrations in the water column, as explained above in section III.B.5 of this memorandum. EPA-HQ-OPP-2011-0374-0038. Without these data, the Agency is unable to assess risks to these organisms specifically and would likely have to extrapolate from surrogate data if they are available, resulting in reduced confidence in the registration review ecological risk assessment overall.

On April 29, 2013, AMVAC submitted a data waiver request for this data requirement, proposing that EPA wait until submission of the same study on DCPA and for the Agency to conduct its assessment using the toxicity endpoints determined for DCPA. MRID 49115401, PAX 5 at 23-24. On March 21, 2014, EPA denied the data waiver request. EPA-HQ-OPP-2011-0374-0049, PAX 66. In the October 16, 2020 Data Delay Letter, EPA notified AMVAC that this

DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. On December 17, 2020, AMVAC submitted a second data waiver request for this requirement. MRID 51398103, PAX 22. On April 27, 2022, EPA denied the second waiver request. This data requirement remains outstanding.

10. Guideline No. 850.1400, Fish early life-stage (sheepshead minnow), TPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.630, as explained in further detail in Guideline No. 850.1400, by January 31, 2014. EPA required a study of TPA's early-life stage toxicity to estuarine/marine fish, due in part to potentially high concentrations in the water column, as explained above in section III.B.5 of this memorandum. EPA-HQ-OPP-2011-0374-0038. Without these data, the Agency is unable to assess risks to these organisms specifically and would likely have to extrapolate from surrogate data if they are available, resulting in reduced confidence in the registration review ecological risk assessment overall.

On April 29, 2013, AMVAC submitted a data waiver request for this data requirement, proposing that EPA wait until submission of the same study on DCPA (submitted to EPA only on June 7, 2022) and for the Agency to conduct its assessment using the toxicity endpoints determined for DCPA. MRID 49115401, PAX 5 at 23-24. On March 21, 2014, EPA denied the data waiver request. EPA-HQ-OPP-2011-0374-0049, PAX 66. In the October 16, 2020 Data Delay Letter, EPA notified AMVAC that this DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. On December 17, 2020, AMVAC submitted a second data waiver request for this

requirement. MRID 51398103, PAX 22. On April 27, 2022, EPA denied the second waiver request. This data requirement remains outstanding.

11. Guideline No. 850.2100, Acute avian oral toxicity (passerine species) (DCPA)

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.630, as explained in further detail in Guideline No. 850.2100, by January 31, 2014. EPA required a study of the acute oral toxicity of DCPA in a passerine bird species (passerines are "perching birds," or more colloquially, song birds). EPA-HQ-OPP-2011-0374-0023. Without these data, the Agency is unable to assess risks for birds of this type specifically, resulting in reduced confidence in the registration review ecological risk assessment overall.

On April 29, 2013, AMVAC submitted a novel protocol for the conduct of a responsive study. PAX 5 at 3. On February 24, 2014, EPA responded and recommended that AMVAC use a previously-approved protocol for the study. On March 6, 2014, AMVAC agreed to use the previously-approved protocol and requested an extension of the submission deadline to October 30, 2014.[13] On September 30, 2014, AMVAC submitted a study. MRID 49477601. On October 16, 2020, EPA informed AMVAC that the study was currently being reviewed. EPA-HQ-OPP-2011-0374-0013, PAX 21. On April 27, 2022, EPA informed AMVAC that additional data were required to satisfy the DCI. The study submitted by AMVAC in 2014 was not conducted pursuant to the agreed-upon protocol or consistent with Guideline 850.2100, particularly with concern to doses tested, and did not satisfy the DCI data requirement. Pursuant to the guideline, AMVAC should have tested doses up to the maximum expected environmental concentration on food items, which may require the dosing method to switch to the use of dietary-based test

[13] EPA does not have a written record granting AMVAC's request in writing, but as AMVAC ultimately submitted an (inadequate) study on September 30, 2014, the question of whether the original deadline or the extended deadlines applies here is not relevant.

methods. The estimated upper-bound residues based on current registered products are more than twice the level for which no effects were observed for any avian species that has been tested (*e.g.*, zebra finch and bobwhite quail), resulting in uncertainty as to whether lethal effects could still occur at expected concentrations. This data requirement remains outstanding.

12. Guideline No. 850.4100, Seedling emergence (lettuce only), DCPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.660, as explained in further detail in Guideline No. 850.2100, by January 31, 2014. EPA required a study of DCPA's effects on non-target plants. On January 29, 2014, AMVAC submitted a study. MRID 49307513, PAX 27. On October 16, 2020, EPA informed AMVAC that the study was currently being reviewed. EPA-HQ-OPP-2011-0374-0013, PAX 21. On April 27, 2022, EPA informed AMVAC that the study was acceptable as to all tested species with the exception of lettuce and ryegrass, and that additional data were required to satisfy the DCI, as to lettuce only. EPA-HQ-OPP-2011-0374-0055, PAX 59. Without these data, the Agency is unable to assess the risks of DCPA exposure on seedling emergence of terrestrial plants that are similar to and represented by lettuce, impacting confidence in the terrestrial plant risk assessment overall. This data requirement, as it applies to lettuce, remains outstanding.

13. Guideline No. 850.4500, Algal toxicity test, Tier I/II (marine diatom only), TPA

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.660, as explained in further detail in Guideline No. 850.4500 (formerly designated as 850.5400), by January 31, 2014. EPA required a study of TPA's toxicity to several aquatic microorganisms, including a marine diatom. On April 29, 2013, AMVAC submitted a data waiver request. MRID 49115401, PAX 5 at 23. EPA denied the request on March 21, 2014. In the October 16, 2020 Data Delay Letter, EPA notified AMVAC that this DCI data requirement remained outstanding,

and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21. On December 17, 2020, AMVAC submitted a second data waiver request, citing two studies (MRIDs 51499401 and 514499402) in support. On January 25, 2022, EPA determined that the data submitted by AMVAC satisfied the DCI as to freshwater green algae species only. On April 27, 2022, EPA denied the remainder of AMVAC's data waiver request as to marine diatom species. EPA-HQ-OPP-2011-0374-0038. This data requirement remains partially outstanding. Without these data, the Agency is unable to assess the risks of TPA exposure to the marine diatom specifically, impacting confidence in the aquatic risk assessment overall.

14. Non-guideline, Chronic sediment toxicity (*Chironomus*), DCPA

Pursuant to EPA's authority under 40 C.F.R. § 158.30, the DCI required the citation or submission of data on the chronic toxicity of residues of DCPA in the sediment to the freshwater midge, by January 31, 2015 (a midge is a type of small fly that can be an important food source for fish, birds, and other insects). Without these data, the Agency is unable to assess the risks to these organisms specifically, reducing confidence in the ecological risk assessment overall.

On April 29, 2013, AMVAC submitted a protocol for this study. PAX 5 at 18-19. On March 20, 2014, EPA reviewed the protocol and recommended revisions. EPA-HQ-OPP-2011-0374-0048, PAX 60 attachment 1. On March 18, 2016, AMVAC submitted data in response to this requirement. MRID 49865802. On October 16, 2020, EPA informed AMVAC that the study was being reviewed. EPA-HQ-OPP-2011-0374-0013, PAX 21. On April 27, 2022, EPA informed AMVAC that additional data are required to satisfy the DCI. EPA-HQ-OPP-2011-0374-0055, PAX 59. Specifically, the results reported for the negative control were likely due to the solvent used, not DCPA. *Id.* This data requirement remains outstanding.

15. Non-guideline, Chronic sediment toxicity (*Leptocheirus*), DCPA

Pursuant to EPA's authority under 40 C.F.R. § 158.30, the DCI required the citation or submission of data on the chronic toxicity of residues of DCPA in the sediment to the estuarine/marine amphipod (a type of small crustacean, generally an important component of the aquatic ecosystem), by January 31, 2015. Without these data, the Agency is unable to assess the risks to these organisms specifically, reducing confidence in the ecological risk assessment overall.

On April 29, 2013, AMVAC submitted a protocol for this study. PAX 5 at 18-19. On March 20, 2014, EPA reviewed the protocol and recommended revisions. EPA-HQ-OPP-2011-0374-0048, PAX 60 attachment 1. On December 15, 2014, AMVAC informed EPA that it was further developing the methodology for conducting the study and would submit an update on March 31, 2015. On March 30, 2015, AMVAC noted that it was still developing the methodology, and planned to submit a second update by September 2015. On September 22, 2015, AMVAC noted that it was still developing the methodology, and planned to submit a third update by March 2016.

On March 15, 2016, AMVAC submitted a data waiver request. MRID 49865803. EPA denied that request on June 27, 2016, but indicated that AMVAC could potentially satisfy the data requirement with an alternate study conducted under Guideline 850.1740, which would determine whether the chronic sediment toxicity study was necessary. EPA-HQ-OPP-2011-0374-0050, PAX 74. In the October 16, 2020 Data Delay Letter, EPA notified AMVAC that this DCI data requirement remained outstanding, and asked how AMVAC intended to satisfy the requirement. EPA-HQ-OPP-2011-0374-0013, PAX 21.

On December 17, 2020, AMVAC stated that it would not be commencing a study to satisfy the data requirement, arguing that the lack of this data would not impact EPA's

registration review risk conclusions as to DCPA and sediment-dwelling organisms. PAX 22. On April 27, 2022, EPA reiterated to AMVAC that this data requirement remains outstanding, and that AMVAC could potentially satisfy the requirement with an alternate study under Guideline 850.1740, designed to provide acute sediment toxicity data.

16. Guideline No. 860.1300, Nature of the residue: poultry

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.1410, as explained in further detail in Guideline No. 860.1300, by January 31, 2015. EPA required a study of the chemistry of DCPA and its degradates as residues in poultry. These data are needed to conduct a complete dietary risk assessment. [14] It is important to note that the data required by this study, and AMVAC's requests for waiver, are interconnected with the field accumulation in rotational crops data (Guideline 860.1900) required by the DCI discussed in section III.B.19 of this memorandum, below, due to the potential for residues in crops planted after the preceding crop was treated with DCPA that, in turn when fed to livestock, could result in residues in livestock commodities. Without these data, EPA cannot confirm that poultry commodities do not contain DCPA residues and contribute to dietary exposure associated with the use of DCPA and thus cannot confirm that such commodities are not adulterated.

On April 19, 2013, AMVAC submitted a data waiver request based on this data requirement no longer being necessary if AMVAC removed uses of DCPA on alfalfa, a poultry feed item, from product labels. MRID 49115401. At the time of the request, while alfalfa was

[14] FIFRA Section 2(bb) defines unreasonable risk to include "human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under [Section 408 of the FFDCA]." 7 U.S.C. § 136(bb) (citing 21 U.S.C. § 346a); *supra* section II.A. Where residues are present in food commodities that are not covered by a tolerance or tolerance exemption, those commodities are adulterated and may not be distributed in commerce. 21 U.S.C. §§ 346a(a)(1), 342(a)(2)(B), 331(a).

included on AMVAC's technical DCPA label, no DCPA end-use products[15] were labeled for use on alfalfa and EPA had not set a DCPA residue tolerance for alfalfa. EPA-HQ-OPP-2011-0374-0042, PAX 26. On October 23, 2013, EPA responded to AMVAC's data waiver request, noting that the Agency would consider waiving the 860.1300 poultry residue data requirement depending on the outcome of required 860.1900 residue studies on the major poultry feedstuffs, corn and soybean, which may contain DCPA residues as a result of crop rotations and from soil drift (*i.e.*, treated soil blowing from a treated crop field to an untreated adjacent field). *Id*. There are "indirect or inadvertent residue" tolerances for DCPA on corn and soybeans, allowing for some residues as a result of soil drift. 40 C.F.R. § 180.185(d). EPA noted that, depending on the outcome of required 860.1900 residue studies on the major feedstuffs corn and soybeans, the dietary burden for poultry eating corn, soybeans, and other feedstuffs that may have DCPA residues may be low enough to result in negligible residues of DCPA in poultry commodities, and possibly negating the need for the outstanding 860.1300 data. EPA-HQ-OPP-2011-0374-0042. To date, AMVAC has not submitted these required data (860.1300 or, alternately, 860.1900) and has not amended its product label to restrict or prohibit certain crop rotations in a manner that would obviate the need to conduct studies of DCPA residues on poultry (*e.g.*, only allowing rotation to crops with established tolerances for DCPA, with a minimum PBI of 8 months). *See infra* section III.B.19; PAX 32. This data requirement remains outstanding.

17. Guideline No. 860.1340, Residue analytical method: livestock commodities

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.1410, as explained in further detail in Guideline No. 860.1340, by January 31, 2015. EPA required

[15] Alfalfa is listed as a use on AMVAC's technical formulation label (EPA Reg. 5481-495) along with several other crops, many for which there are no registered direct uses, but for which tolerances are established for indirect or inadvertent residues caused by soil drift. 40 C.F.R. § 180. 185(d).

submission of an analytical method for detecting residues of DCPA and its degradates in livestock commodities (i.e., meat, milk, eggs). It is important to note that the data required by this study, and AMVAC's requests for waiver, are interconnected with the field accumulation data (Guideline 860.1900) required by the DCI discussed in section III.B.19 of this memorandum, below. Without an acceptable method, there is no approved means for quantifying residues in livestock commodities, which means that tolerances, if needed, could not be established. 21 U.S.C. § 346a(b)(3). As noted in the previous section, EPA cannot confirm that these commodities are not adulterated without additional data.

On April 19, 2013, AMVAC submitted a data waiver request based on this data requirement no longer being necessary if AMVAC removed uses of DCPA on certain minor livestock feedstuffs from product labels. MRID 49115401. On October 23, 2013, EPA responded to AMVAC's data waiver request, noting that the Agency would consider waiving the 860.1340 livestock commodity analytical method data requirement depending on the outcome of 860.1900 residue studies on the major livestock feedstuffs, corn and soybean, which may contain DCPA residues as a result of crop rotations and from soil drift. EPA-HQ-OPP-2011-0374-0042, PAX 26. EPA noted that, depending on the outcome of those major crop residue studies, the dietary burden for ruminants (*e.g.*, cattle, goats, sheep) eating corn, soybeans, and other feedstuffs that may have DCPA residues may be low enough to result in negligible residues of DCPA in livestock commodities, and possibly negating the need for the outstanding 860.1340 data. EPA-HQ-OPP-2011-0374-0042. To date, AMVAC has not submitted these required data (860.1340 or, alternately, 860.1900) and has not amended its product label to restrict or prohibit certain crop rotations in a manner that would obviate the need to conduct studies of DCPA residues on livestock commodities (*e.g.*, only allowing rotation to crops with established tolerances for

DCPA, with a minimum plantback interval (PBI) of 8 months). *See infra* section III.B.19; PAX 32. This data requirement remains outstanding.

18. Guideline No. 860.1480, Meat/milk/poultry/eggs (livestock feeding study)

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.1410, as explained in further detail in Guideline No. 860.1480, by January 31, 2015. EPA required a study of the transfer of residues of DCPA and its degradates in animal feed items to livestock. It is important to note that the data required by this study, and AMVAC's requests for waiver, are interconnected with the field accumulation in rotational crops data (Guideline 860.1900) required by the DCI discussed in section III.B.19 of this memorandum, below. Without these data, EPA cannot account for residues of DCPA and its degradates in livestock commodities present as the result of consuming animal feed items that contain such residues.

On April 29, 2013, AMVAC submitted a data waiver request, based on this data requirement no longer being necessary if AMVAC removed uses of DCPA on alfalfa, white potatoes, and peas from its technical label. PAX 5 at 15-16. MRID 49115401. On October 23, 2013, EPA responded to AMVAC's data waiver request, noting that the Agency would consider waiving the 860.1480 residue data requirement depending on the outcome of 860.1900 residue studies on the major livestock feedstuffs, corn and soybean, which may contain DCPA residues as a result of crop rotations and from soil drift. EPA-HQ-OPP-2011-0374-0042, PAX 26. EPA noted that, depending on the outcome of those major crop residue studies, the dietary burden for animals eating corn, soybeans, and other feedstuffs that may have DCPA residues may be low enough to result in negligible residues of DCPA, and possibly negating the need for the outstanding 860.1480 data. EPA-HQ-OPP-2011-0374-0042. To date, AMVAC has not submitted these required data (860.1480 or, alternately, 860.1900) and has not amended its product label to

restrict or prohibit certain crop rotations in a manner that would obviate the need to conduct studies of DCPA residues on livestock (*e.g.*, only allowing rotation to crops with established tolerances for DCPA, with a minimum PBI of 8 months). *See infra* section III.B.19; PAX 32. This data requirement remains outstanding.

19. Guideline No. 860.1900, Field accumulation in rotational crops

The DCI required the citation or submission of data responsive to 40 C.F.R. § 158.1410, as explained in further detail in Guideline No. 860.1900, by January 31, 2016. EPA required a study of DCPA uptake by crops rotated into fields that were previously treated with DCPA. Current labels for products containing DCPA do not broadly prohibit the planting of crops in fields that have previously been treated with DCPA products; labels for these products merely warn that the replanting of crops other than those included on the label in previously treated soils within eight months of product application may result in crop injury. Without restrictions on planting other crops, it remains possible for crops to be planted in formerly treated fields, and for the uptake of DCPA and its degradates by these crops to occur and result in residues in the crops. Without this data, EPA cannot determine if residues of DCPA and its degradates are present in the rotated crops, which directly impacts the Agency's ability to conduct the dietary risk assessment.

On April 29, 2013, AMVAC submitted a request for EPA to consider two previously-submitted studies in satisfaction of the requirement. MRID 49115401, PAX 5 at 15-16. On October 23, 2013, EPA determined that the other studies were not relevant to the data requirement and that AMVAC would need to submit additional rotational crop data and to make changes to the end-use product labels specifying which crops are allowed for rotational planting (and what "plant back" interval would be needed) following the most recent use of DCPA. EPA-HQ-OPP-2011-0374-0042, PAX 26. On January 29, 2014, AMVAC provided some storage

stability data in response to this data requirement. MRID 49307500, PAX 27. On July 7, 2014, EPA determined that the additional data were not responsive to the data requirement and reiterated that additional field trial data were required to determine appropriate DCPA tolerances for rotated crops. EPA-HQ-OPP-2011-0374-0040, PAX 28.

On August 11, 2014, AMVAC responded to EPA's determinations, again citing existing data and proposing label restrictions that did not appropriately address[16] the crop rotation restrictions that would be needed to obviate this data requirement as justification for its position. Rather than prohibiting rotation to any other crop for which DCPA is not registered, the proposed labeling cautions the user that rotation to non-registered crops within eight months after application of DCPA could result in crop injury. While this labeling would provide potentially important information to the grower, it does not address the Agency's potential dietary risk concerns or the potential for subsequent crops to be adulterated due to the lack of a tolerance.

On February 17, 2015, EPA responded, reiterating its prior position and noting that the Agency could consider amending the data if AMVAC made certain specific modifications, outlined in a table, to DCPA end-use product labels. EPA-HQ-OPP-2011-0374-0043, PAX 32. To date, AMVAC has not submitted the required data or amended its product labels in a manner that would obviate the need to conduct crop rotational studies on DCPA (*e.g.*, only allowing rotation to crops with established tolerances for DCPA, with a minimum PBI of 8 months). AMVAC has not requested label amendments consistent with the modifications suggested in

[16] AMVAC proposed label restrictions that focused on crop injury from planting crops not listed on its DCPA labels within 8 months of DCPA application. This restriction does not address possible crop adulteration resulting from a lack of tolerances for those crops not listed on the label.

EPA's February 17, 2015 response; the only amendments requested by AMVAC would not accomplish the same purpose. This data requirement remains outstanding.

20. Non-guideline, Comparative thyroid study, DCPA

Pursuant to EPA's authority under 40 C.F.R. § 158.30, the DCI required the citation or submission of a comparative thyroid toxicity study (a comparative thyroid assay, or "CTA") by January 31, 2015, due to toxicity data gaps identified in the May 27, 2011 scoping document for registration review of DCPA. *See* EPA-HQ-OPP-2011-0374-0004.[17] There is no codified data requirement for the CTA nor an OCSPP Guideline available, nevertheless, EPA has successfully worked with other registrants on the details for conducting the necessary component studies to illuminate the effects of pesticide active ingredients, such as DCPA, on thyroid development and function in pregnant females, fetuses, and offspring. The CTA is conducted using laboratory animals and the results are used to quantify thyroid toxicity during different stages of development in humans. The data that are generated by conducting the CTA allow the EPA to derive a safe dose level (reference dose) that would protect the developing nervous system from thyroid hormone disrupting chemicals. Given that the thyroid effects were observed in guideline toxicity studies on DCPA, the Agency required the definitive CTA. Without the CTA data, the Agency cannot conduct a human health risk assessment that is assuredly protective of thyroid effects, including for the developing fetus. Without a sound human health risk assessment, the Agency is unable to determine whether or not DCPA satisfies the standard for registration under FIFRA. *See* 40 C.F.R. § 158.30.

[17] The 2011 scoping document referenced a July 8, 2002 Human Health Risk Assessment conducted by EPA during the Agency's evaluation of an application for new uses of a different DCPA product. RX 2. This document noted that several thyroid studies in rats were required to support EPA's confidence in its risk assessment. *Id.*

EPA reviewed preliminary data submitted by AMVAC, which suggest that DCPA can affect thyroid function at lower doses than previously known, and that DCPA may affect a fetus at lower doses than those that adversely affect adults. These effects are detailed below. Based on the preliminary data, EPA cannot make a reliable determination of "reasonable certainty of no harm" for aggregate exposures to evaluate whether current tolerances are safe under the FFDCA, or a finding that there are unreasonable adverse effects related to occupational exposures under FIFRA.

On April 29, 2013, AMVAC submitted protocols[18] for conducting four preliminary thyroid studies in response to the DCI (a range-finding study in juveniles, a comparative study in young adult/post-natal day 11 pups, a repeat-dosing study in young adult/post-natal day 11pups, and a gestational exposure comparative thyroid study). PAX 5 at 3. On November 19, 2013, EPA completed review of the four protocols and determined that they were inadequate based on issues related to dose selection, time of sample collection, method of sacrifice, and purity of test material. EPA-HQ-OPP-2011-0374-0041, PAX 6. EPA recommended that AMVAC submit a new protocol for one of the preliminary studies, the range-finding study. On November 26, 2014, AMVAC submitted a revised range-finding[19] protocol in response to EPA's determination that the initial protocols were inadequate. In a March 19, 2015 call, EPA provided feedback concerning AMVAC's submitted protocols.

[18] Prior to conducting a study, particularly non-codified studies, registrants generally develop a written protocol to "clearly indicate[] the objectives and all methods for the conduct of the study. 40 C.F.R. § 160.120(a); s*ee generally* 40 C.F.R. Part 160, subpart G. Registrants may submit protocols to EPA, which may make recommendations or suggestions that the registrant can implement prior to conducting the study. EPA's recommendations are intended to ensure the methods used are reliable (*i.e.*, statistically valid), are likely to provide reproducible results, and are likely to generate reliable data.

[19] A range-finding study is the initial study for some toxicology studies, such as the comparative thyroid assay, designed to find the dose ranges at which adverse effects are likely to occur so that doses can be chosen which will allow determination of a No Observed Adverse Effect Level (NOAEL) and Lowest Observed Adverse Effect Level (LOAEL) in longer-term studies. The NOAEL is typically used as the starting point for quantifying risks.

On June 29, 2015, EPA reiterated that AMVAC conduct a CTA study looking at specific thyroid parameters in pregnant animals, fetuses, postnatal animals, and adult animals, in part due to findings from the Agency's Endocrine Disruptor Screening Program Weight of Evidence ("WOE") Conclusions that data obtained from adult animals could not be used to develop toxicity endpoints for younger animals. EPA-HQ-OPP-2011-0374-10. EPA noted that a CTA study would address concerns for the potential ability of DCPA to disrupt thyroid functions in pregnant females, fetuses, and offspring (postnatal). *Id.*

In a January 25, 2017 email, AMVAC informed EPA that the range-finding study would have to be repeated because the testing lab was unable to quantify thyroid hormone levels in fetal plasma. AMVAC provided an estimated submission date, the end of 2018, for the range-finding CTA report for the fetal lifestage. In a March 17, 2017 email, EPA requested that AMVAC provide quarterly updates on the progress of the CTA studies (positive control study; dose range-finding study for the fetal lifestage; and the dose range-finding study for the postnatal lifestage). AMVAC submitted several updates via email between May 2017 and April 2021. *See, e.g.,* PAX 10 and 11. On August 17, 2017, AMVAC submitted one component of the CTA, a positive control study. MRID 50357301, PAX 12. The purpose of the study was to generate positive control data for known effects on thyroid hormone levels and histopathology to compare to the DCPA developmental thyroid studies in fetuses and postnatal lifestages. The positive control used in the study was a compound other than DCPA, which AMVAC noted "has frequently been used for this purpose in validation of thyroid studies."

On November 16, 2017, EPA recommended that the new range-finding study incorporate certain aspects, including the potential for DCPA to transfer from a mother's milk to offspring to show that pups would be exposed through milk or, if not, would need to be dosed directly. EPA-

HQ-2011-0374-0045, PAX 14. On November 17, 2017, AMVAC submitted a study report on validation of the procedure for measuring thyroid hormone levels in rat serum. On June 29, 2018, AMVAC submitted a preliminary pre-natal range-finding study. On September 17, 2019, EPA provided its review of the preliminary range-finding study in adult animals and made several recommendations for the final study. EPA-HQ-OPP-2011-0374-0047. In a June 23, 2020 email, AMVAC informed EPA that the range-finding study for the postnatal lifestages (adults and offspring) would be submitted by December 2020. In an August 6, 2020 email, AMVAC revised this predicted submission date to March 2021.

In 2018, AMVAC completed an oral gavage dose range finding thyroid study that measured thyroid toxicity following gestation. MRID 50663603. In this study of pregnant female rats, dosed at 0.1 mg/kg/day, unexpected thyroid effects were observed in the rat fetuses for two parameters: thyroid hormone T3 concentrations increased by 16-20% and thyroid stimulating hormone ("TSH") concentrations decreased by 21-25%. *Id.* At the next-highest dose of 1 mg/kg/day, effects in the rat fetuses on the thyroid included decreases in T3 (13-18%), T4 (17-25%), and TSH (25-36%). *Id.* At higher dose levels in the rat fetuses, greater than or equal to 10 mg/kg/day, other changes in thyroid parameters were also recorded. *Id.* In 2021, AMVAC completed a dose range-finding study examining milk transfer and thyroid hormone levels following lactation. MRID 51591701. In its review of this 2021 study, EPA found problems with dose formulation preparation making quantitative use of the concentration data difficult; however, the study results qualitatively showed that DCPA was detected in maternal milk samples at all dose levels.

The unexpected thyroid effects, and the low doses at which such effects appeared, suggest that the last several human health risk assessments for DCPA, including the assessment

completed for EPA's 1998 Reregistration Eligibility Decision ("RED")[20], may not be protective of a potentially sensitive lifestage (*i.e.*, the growing fetus).The preliminary DCPA data evaluated by EPA (MRIDs 51591701 and 50663603) provide evidence that the fetus is exposed to DCPA *in utero*, the offspring are exposed to DCPA through lactation, and the fetus potentially may be more sensitive to thyroid function perturbations due to DCPA exposure compared to maternal animals. Thyroid hormone perturbations in the fetal lifestage were observed at dose levels 10 to 500 times lower than the points of departure ("PODs," or the highest doses at which adverse effects to test animals were not observed, based on earlier toxicology studies) used previously for assessing DCPA risk, indicating those PODs may not be protective. Without complete data on the thyroid toxicity of DCPA in test animals and their offspring ("comparative" data), the Agency is unable to complete the scientifically robust and defensible human health risk assessment needed to evaluate whether DCPA products continue to meet the standard for registration under FIFRA.

In the October 16, 2020 Data Delay Letter, EPA informed AMVAC that the CTA data (dose range-finding study for the postnatal lifestage and the definitive final CTA) remained outstanding. EPA-HQ-OPP-2011-0374-0013, PAX 21. On December 17, 2020, AMVAC informed EPA that it was developing data to satisfy the CTA data requirement. PAX 22.

On March 25, 2021, AMVAC submitted a draft report for the post-natal (adult and offspring) range-finding study and a protocol for the definitive CTA study. *See* PAX 23. On May 27, 2021, AMVAC requested that EPA review the protocol it submitted on March 25 and submitted the final post-natal range-finding study report. On July 15, 2021, EPA provided

[20] Re-registration was the process for periodically reassessing registered pesticides, conducted under FIFRA Section 4, that pre-dates EPA's current statutorily-mandated process of registration review. 7 U.S.C. § 136a-1. DCPA Reregistration Eligibility Decision, *available at* https://archive.epa.gov/pesticides/reregistration/web/pdf/0270red.pdf.

comments and recommendations on the definitive CTA protocol. EPA-HQ-OPP-2011-0374-0056. On August 20, 2021, AMVAC provided responses to EPA's comments.

In a January 26, 2022 email, AMVAC stated that the in-life portion of the definitive CTA study had been completed in September 2021, the draft study report would be submitted by February 18, 2022, and projected submission of the definitive CTA final report to EPA by the end of June 2022. This email was the first of the quarterly updates to provide a prospective date for submitting the definitive study to EPA. In a February 7, 2022 email, EPA requested additional information to facilitate review of the fetal and postnatal range-finding CTA studies. PAX 25. In a February 9, 2022 email, EPA requested additional details on the fetal and post-natal range-finding CTA studies. AMVAC provided the requested updates on February 9 and 15, 2022, respectively.

To-date, AMVAC still has not submitted the required definitive CTA study or the draft definitive CTA report for the Agency to review preliminary results, despite repeated statements over the course of more than three years that submission would be completed. Given the numerous draft protocols, rounds of Agency review, and the numerous interactions with EPA on the different components needed to conduct the definitive CTA over the past nine years, the Agency is skeptical that the Final Report, now promised for June 2022, will be acceptable and will satisfy the data requirement. This data requirement remains outstanding and EPA is unable to complete the scientifically robust and defensible human health risk assessment needed to evaluate whether DCPA products continue to meet the standard for registration under FIFRA, even if using conservative assumptions about DCPA's thyroid toxicity.

C. Notice of Intent to Suspend

As a result of AMVAC's failure to satisfy the 20 data requirements discussed above in section III.B. of this memorandum, EPA issued the NOITS for DCPA on April 27, 2022,

pursuant to FIFRA Section 3(c)(2)(B)(iv). EPA-HQ-OPP-2011-0374-0052, PAX 1 (citing 7 U.S.C. § 136a(c)(2)(B)(iv)). EPA published the NOITS in the Federal Register on April 28, 2022. 87 Fed. Reg. 25262, PAX 2. The NOITS provided a detailed description of the outstanding data requirements and the history of communications between EPA and AMVAC on those requirements. *Id.* Although not required either to substantiate the data requirements of the DCI or to support suspension of AMVAC's registration pursuant to FIFRA Section 3(c)(2)(B)(iv), EPA included in the NOITS a detailed explanation of the reasons it still required the outstanding data. *Id.* For example, EPA explained that it could not complete a scientifically-robust and defensible human health risk assessment—required for the Agency to complete registration review of DCPA under FIFRA Section 3(g)—due to the lack of data examining the fetal thyroid toxicity of DCPA and the lack of data on TPA's persistence in water. *Id*.; *see* 7 U.S.C. § 136a(g); 40 C.F.R. 155.40(a)(1). The NOITS provided AMVAC with instructions for how to avoid suspension of the registration, to wit: (1) requesting a hearing pursuant to FIFRA Section 3(c)(2)(B)(iv) or (2) satisfying the outstanding data requirements of the DCI, as listed and described in Attachments II and III to the NOITS. 87 Fed. Reg. 25262, PAX 2.

The NOITS also included the following determinations as to existing stocks of AMVAC's product, EPA Reg. No. 5481-495:

> 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.

Id. The NOITS clarified that persons other than AMVAC could "continue to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person." *Id.* It is important to note that the NOITS applies only to AMVAC's registration for the technical-grade DCPA product, EPA Reg. No. 5481-495, because the data requirements of the DCI pertained only to that registration. Other registrations of pesticide products containing DCPA, including end-use pesticide products formulated by AMVAC from the registration subject to the NOITS, would not be suspended. Stated another way, if AMVAC's registration EPA Reg. No. 5481-495 is suspended, individuals other than AMVAC that hold stock of the product can continue to use that registered product and anyone, including AMVAC, may continue to use and sell end-use products formulated from the suspended product, with the caveat that AMVAC may not formulate any additional end-use products from the suspended product after the date the suspension becomes effective.

Pursuant to its right under FIFRA Section 3(c)(2)(B)(iv), on May 27, 2022, AMVAC requested a hearing. FIFRA-HQ-2022-0002, Request for Hearing and Statement of Objections (May 27 2022).

IV. ARGUMENT

This case presents only two related questions to the Presiding Officer: (1) whether AMVAC has, within the timeframes required by the Agency, failed to take appropriate steps to secure the data required by the DCI and (2) whether the terms of the NOITS concerning existing stocks of AMVAC's product are consistent with FIFRA.

As discussed in this memorandum, with respect to at least three data requirements AMVAC does not contest that it failed to take appropriate steps to fulfill the DCI data requirements. EPA maintains that AMVAC failed to take appropriate steps for all 20 such

requirements, within the timeframes required by the Agency, as described above. Even a single failure to submit necessary data responsive to a DCI is sufficient for EPA to suspend a product subject to the DCI.

As to the second question, the existing stocks provisions of the NOITS are clearly consistent with the requirements of FIFRA, *i.e.*, the requirement that EPA ensure DCPA's continued use will not cause unreasonable adverse effects on man or the environment, a determination that can only be made when sufficient data allow EPA to assess risks.

Accordingly, the Presiding Officer can answer the questions presented based on the facts presented in this memorandum and, as a matter of law, enter an order suspending AMVAC's registration until the company complies with the EPA DCI.

A. Standard for an Accelerated Decision

Regulations pertaining to hearings arising under FIFRA Section 6, including hearings pertaining to cancellation and suspension of registrations, permit the ALJ to issue an accelerated decision similar to a summary judgment under the Federal Rules of Civil Procedure. Specifically, 40 C.F.R. § 164.91(a) provides that an Administrative Law Judge, in their discretion,

> may at any time render an accelerated decision in favor of Respondent as to all or any portion of the proceeding, including dismissal without further hearing or upon such limited additional evidence such as affidavits as he may receive, . . . [by finding] that there is no genuine issue of material fact and that the [R]espondent is entitled to judgement as a matter of law.

Many provisions of 40 C.F.R. Part 164, including 40 C.F.R. § 164.91, are analogous to those in the Federal Rules of Civil Procedure. *Cf.* Fed. Rul. Civ. P. 56(a) (providing for summary

judgment where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law").[21]

This motion turns on the dispositive and limited question of whether, as a matter of law, AMVAC has taken appropriate steps to fulfill the requirements of the DCI within the timeframes required by the agency. FIFRA Section 3(c)(2)(B)(iv) invests EPA with the sole authority to determine whether an applicant "has complied fully with the requirements" that serve as the basis for lifting suspension of its registration. 7 U.S.C. § 136a(c)(2)(B)(iv). EPA maintains that the clear Congressional intent investing OCSPP with authority to determine full compliance in the context of lifting a suspension suggests comparable authority with respect to the identical determination of whether the data requirements have been satisfied prior to a suspension action.

It is important to note that AMVAC bears the burden of proof to demonstrate that it has taken steps to fulfill the terms of the DCI by submitting the required data. 40 C.F.R. § 164.80(b) ("On all issues arising in connection with the hearing, the ultimate burden of persuasion shall rest with the proponent of the registration."); *see Dow Chem. Co. v. Ruckelshaus*, 477 F.2d 1317, 1324-25 (8th Cir. 1973) ("[T]he registrant has a continuing burden of proof to establish that its product is entitled to registration."). The burden of demonstrating that a pesticide product satisfies the statutory criteria for registration is at all times on the proponents of the initial or continued registration and continues as long as the registration is in effect. 40 C.F.R. § 164.80(b); *see also Indust. Union Dept. v. Am. Petroleum Inst.*, 448 U.S. 607, 653 n.61 (1980); *Stearns Electric Paste v. EPA*, 461 F.2d 293 (7th Cir. 1972); *Envt'l Defense Fund v. EPA*, 510 F.2d 1292, 1297 (D.C. Cir. 1975).

[21] 40 C.F.R. Part 164 is also analogous to 40 C.F.R. Part 22, the regulations governing assessment of civil penalties and enforcement under FIFRA and other environmental statutes administered by EPA. *Cf.* 40 C.F.R. § 22.20.

B. No Other Matters are Appropriate for Resolution in this Hearing

Under FIFRA Section 3(c)(2)(B)(iv), "the only matters for resolution [] shall be whether [AMVAC] has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether [EPA's] determination with respect to the disposition of existing stocks is consistent with [FIFRA]." 7 U.S.C. § 136a(c)(2)(B)(iv). Congress intended FIFRA to be the tool for EPA to protect human health and the environment from unreasonable adverse effects of pesticide use, and recognized the importance of data to the Agency's determinations necessary to carry out that mission. Under FIFRA 3(c)(2)(A), EPA is required to publish requirements for data to support pesticide registrations and to update them from time to time. 7 U.S.C. § 136a(c)(2)(A). Under FIFRA Section 3(c)(2)(B), EPA has the authority to issue a DCI at any time it determines additional data are necessary to maintain in effect an existing registration. 7 U.S.C. § 136a(c)(2)(B); 40 C.F.R. § 155.48. Those data are important during the registration review of a pesticide as EPA must determine whether the pesticide continues to meet the FIFRA standard, including that it generally will not cause unreasonable adverse effects on the environment. 40 C.F.R. § 155.40(a). Registration review is intended to be based on current scientific knowledge regarding a pesticide and DCIs are commonly used to ensure EPA has such information. 40 C.F.R. §§ 155.40(a)(1) and 155.48.

FIFRA provides EPA with the authority to suspend a pesticide registration where the registrant has not responded to EPA's data requests, which thwarts EPA's ability to determine if the pesticide continues to meet the standard for registration under FIFRA. Although Congress provided registrants with the opportunity to request a hearing on EPA's decision to suspend a registration for failure to provide necessary data, it expressly limited the scope of any such hearing. Congress also provided a very short 75-day period for the completion of the hearing,

further indicating the limited scope of issues; a full review of a registrant's submissions to the Agency and determinations as to other matters would be impractical to address in such a short time frame. Any attempt on the part of AMVAC or other Petitioners to broaden the instant hearing to include other matters, such as the technical sufficiency of its data submissions, the time taken by EPA to review and respond to said submissions, the fact that certain data may be submitted while this hearing is pending, or EPA's rationale for requiring the submission of certain data, are barred by law. 7 U.S.C. § 136a(c)(2)(B)(iv).

"FIFRA provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products." 40 C.F.R. § 158.30(a); *id.* § 158.75. AMVAC had an opportunity to comment on the data that EPA anticipated would be required to complete registration review, but declined to comment. EPA-HQ-OPP-2011-0374-0002; EPA-HQ-OPP-2011-0374-0008. AMVAC's assertion in its Request for Hearing that certain data requirements "are [not] needed to conduct the ecological risk assessment for DCPA for Registration Review" does not justify its failure to comply with the requirements of the DCI and is not appropriate for resolution in this matter. *See* Request for Hearing at 4-5. AMVAC elected to request waivers of certain data requirements under 40 C.F.R. § 158.45, for which EPA retains broad discretion to grant or deny. AMVAC is well aware that it could request an extension of time to respond to a given DCI data requirement, as the company did in fact request such an extension for the study required to satisfy Guideline 850.2100. It did not make such requests as to the other data requirements, yet now, more than eight years later, argues that EPA's timeframes for completion of certain studies were impractical. *See* Request for Hearing at 4-5.

C. EPA has Established that AMVAC Failed to Comply with the 2013 DCI, and that Is Sufficient to Justify the Suspension.

FIFRA authorizes the EPA to suspend a registration where a registrant fails to take appropriate steps to fulfill the requirements of a DCI within the time established by the EPA. The *only* question before the Presiding Officer is whether AMVAC has, within the timeframes required by the Agency, failed to take appropriate steps to secure the data required by the DCI. 7 U.S.C. § 136a(c)(2)(B)(iv). It did not. As described above in section III.B. of this memorandum, as of April 28, 2022, AMVAC failed to fulfill 20 data requirements of the 2013 DCI. The required data were due to EPA by various dates, the latest of which was January 31, 2016. EPA-HQ-OPP-2011-0374-0009, PAX 4. With respect to 11 data requirements, EPA denied AMVAC's request for data waivers, including multiple repetitive requests in 6 instances. *See supra* sections III.B.1, III.B.2, III.B.3, III.B.5, III.B.8, III.B.9, III.B.10, III.B.13, III.B.16, III.B.17, and III.B.18. With respect to five data requirements, AMVAC submitted data that EPA later determined did not satisfy the data requirements of the DCI. *Id.* sections III.B.4, III.B.11, III.B.12, III.B.14, and III.B.19. With respect to one data requirement, AMVAC stated that it did not intend to comply with the requirement of the DCI. *Id.* section III.B.15. With respect to three data requirements, AMVAC acknowledged that the data requirements of the DCI remain outstanding and indicated that it would "initiate work to fulfill the . . . requirement[s] for DCPA," with data submission expected for June 2022 or later, at least six years after the deadlines created by the DCI. *Id.* sections III.B.6, III.B.7, and III.B.20. Although AMVAC has provided occasional updates on its progress towards fulfilling some of the data requirements, EPA does not interpret said updates as requests for extensions of time to respond to the DCI and has not provided any such extension to AMVAC.

In the instant case, the relevant factual basis supporting EPA's request for accelerated judgment is, as a matter of law, partially uncontested by AMVAC. *See supra* sections III.B.6, III.B.7, and III.B.20. Indeed, AMVAC concedes that several of DCI data requirements remain outstanding. *Id.*, *see, e.g.*, Request for Hearing at 52-54 (noting that AMVAC expects to submit materials in response to the DCI in June or July 2022); 78-80 (agreeing, only after having received the NOITS, to submit data in response to a DCI requirement by 2023, after previously declining to respond).

That alone is sufficient under 40 C.F.R. § 164.91(a) for the Presiding Officer to grant EPA's Motion for Accelerated Judgement, finding that AMVAC failed to comply with the terms of the DCI and that, as a matter of law, AMVAC's DCPA technical registration, EPA Reg. No. 5481-495, is suspended until it fully complies with said terms. *See In the matter of E.I. DuPont de Nemours and Co.*, FIFRA-93-H-09, 1995 WL 441853 (EPA 1995) (order granting unopposed motion for accelerated judgement as to one count); *see generally In the matter of Micro Pen U.S.A., Inc.*, FIFRA-09-0881-C-98-06, 1999 WL 362851 (EPA 1999) (order granting EPA's factually and legally unopposed request for judgement in its favor as to liability pursuant to the analogous 40 C.F.R. § 22.20(a), noting that respondent's purported non-admission of fault did not preclude a finding as to liability).

In its Request for Hearing, AMVAC makes several arguments in opposition to suspension of its DCPA product. Primarily, AMVAC argues that it "has been taking appropriate steps to comply with [the DCI]." Request for Hearing at 2. That is insufficient as a matter of law—FIFRA Section 3(c)(2)(B)(iv) is clear that EPA has authority to determine whether a registrant has failed to take appropriate steps to submit required data "within the time required." 7 U.S.C. § 136a(c)(2)(B)(iv). There is no requirement for the Agency to engage in an open-

ended process of negotiating the need for certain data, considering multiple waiver requests, reiterating the need for said data after issuing the DCI, or to provide additional time for a registrant to comply. Moreover, while the parties have engaged in substantial conversation with respect to some data requirements (*e.g.*, the CTA study, section III.B.20, *supra*), with respect to others the factual and legal basis for suspension is substantially more egregious. For example, as discussed in section III.B.2 of this memorandum, above, EPA denied AMVAC's data waiver request in 2017. In 2018, AMVAC indicated that it intended to submit the data, failed to do so in the intervening years, and now proposes to do so at some undefined future date. Request for Hearing at 81-82. With respect to that data requirement, AMVAC argues that "[i]t is unreasonable that EPA made its final position" clear only in documents provided concurrently with the NOITS. *Id.* In addition to being factually incorrect—EPA denied that waiver request in 2017—AMVAC misconstrues the process for satisfaction of data requirements. FIFRA neither requires EPA to continually reaffirm its need for particular data nor to provide additional notice to affected registrants that a data requirement remains outstanding. *See generally*, 7 U.S.C. § 136a(c)(2). AMVAC also makes a related argument that the length of time EPA took to respond to certain waiver requests or data submissions caused the company "to believe that studies likely would not be required based on the results of other studies." Request for Hearing at 3. AMVAC does not articulate a legally-cognizable reliance interest created by the timeline of EPA's responses, or explain why the company presumed that EPA would no longer require certain data despite ongoing conversations concerning other data requirements.

Even though AMVAC has submitted some data in response to the DCI and has made commitments to future submissions, the registration must be suspended until EPA determines that AMVAC has fully complied with the DCI. AMVAC's assertions to EPA that it intends to

submit certain data in the future or that its requests for waiver of certain data required by the DCI obviate the need for that data are insufficient to overcome suspension of the registration. *See* 7 U.S.C. § 136a(c)(2); *cf. In re: Bayer Cropscience LP and Nichino America, Inc.*, 17 E.A.D. 228 at 6, 33 (noting collateral attack on matters outside the strict statutory scope limitations of a hearing are prohibited). With respect to one data requirement, AMVAC previously openly stated that it did not intend to comply with the DCI, and that it is only now taking steps to comply with the DCI after receipt of the NOITS. *Supra* section III.B.15; Request for Hearing at 82, para. 359. EPA maintains that the Congressional intent of FIFRA Section 3(c)(2)(B)(iv) is not such that a post-NOITS commitment to submit data is sufficient to evade suspension. Additionally, given the history of this matter, specifically AMVAC's repeated requests for data waivers after EPA has denied similar waiver requests, EPA has determined that suspension of the registration is the appropriate method to ensure compliance with the DCI. With respect to AMVAC's complaints that EPA only provided its last round of waiver denials contemporaneously with the NOITS, EPA's intention in doing so was to avoid yet another round of receiving and reviewing data waivers similar to those previously denied.

D. Determinations in the NOITS as to Existing Stocks of AMVAC's Registered DCPA Pesticide Product are Consistent with FIFRA

As explained above in section II.F. of this memorandum, FIFRA explicitly provides EPA with broad discretion in the area of existing stocks in the case of suspension of pesticide registrations for failure to submit data. *Cf.* 7 U.S.C. § 136a(c)(2)(B); 56 Fed. Reg. 29362, 29367. Pursuant to longstanding policy, EPA will "generally not allow the registrant-to sell or distribute any existing stocks during the pendency of the suspension," but will generally not place

restrictions on the use of existing stocks by persons other than the registrant.[22] 56 Fed. Reg. 29362, 29367. FIFRA Section 3(c)(2)(B)(iv) allows the imposition of suspension to compel registrants to comply with the provisions of a DCI; allowing continuing sale and use of the pesticide for some period after suspension would diminish the incentive for registrants to comply with the DCI in a timely manner.

Here, if AMVAC's registration EPA Reg. No. 5481-495 is suspended, any individuals other than AMVAC who might hold stock of the product can continue to use that registered product[23] and anyone, including AMVAC, may continue to use and sell end-use products formulated from the suspended product, with the caveat that AMVAC may not formulate any additional end-use products from the suspended product after the date the suspension becomes effective.

EPA's determinations as to existing stocks of AMVAC's DCPA product, EPA Reg. No. 5481-495, are consistent with EPA's policy and more broadly with the purpose of FIFRA. The determinations in the NOITS are substantively similar to other recent instances in which EPA sought suspension of a pesticide product. *See, e.g.*, 80 Fed. Reg. 11669, 11671; 77 Fed. Reg. 31844, 31847; 79 Fed. Reg. 49308, 49310 (collectively, notices of intent to suspend certain pesticide registrations). The existing stocks provisions do not place restrictions on the use of the

[22] While the 1991 Existing Stocks Policy did not address whether EPA would typically allow for continued use of suspended products by the registrant, EPA determined that, in this present case, allowing AMVAC, the only registrant of both technical and end-use products, to continue using the subject technical registration to formulate end-use products that would not be affected by any suspension would be akin to allowing AMVAC continued sale and distribution of the product that was the subject of the DCI. The intention behind the 1991 policy was to cut off the registrant's ability to continue to sell and distribute product when they have failed to provide required data. To allow AMVAC to continue using their technical product would have resulted in a situation where there would be no change in their ability to sell and distribute DCPA products, which is counter to the purpose of a suspension.

[23] EPA is unaware whether AMVAC regularly does sell and distributed the subject technical product, but acknowledges that there are no other U.S. registrants of DCPA products and therefore no other EPA-registered products using this technical as a source.

suspended products by persons other than AMVAC, and do not place restrictions on other AMVAC DCPA pesticide products that are not subject to the DCI.

Under FIFRA Section 6(a), EPA "may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended [] under [FIFRA Section 3], to such extent, under such conditions, and for such uses as [EPA] determines that such sale or use is not inconsistent with the purposes of [FIFRA]." 7 U.S.C. § 136d(a). 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. Because essential required data are not available, EPA is unable to determine the magnitude of the risks associated with the continued use of DCPA. Quantifying the magnitude of these risks is essential to EPA's ability to determine that use of the pesticide does not pose unreasonable risks to man or the environment under FIFRA, which requires an understanding of the potential risks and the economic and social benefits associated with use of the pesticide. *See* 7 U.S.C. § 136(bb). Although EPA acknowledges that DCPA end-use pesticides are beneficial to a number of agricultural users, such considerations are irrelevant to the Agency's decision to suspend AMVAC's technical DCPA product. As explained previously, the burden of continued registration for DCPA remains with AMVAC; EPA need not decide whether the uncertain risk of continued use of DCPA is outweighed by its benefits. *Supra* section IV.A. In any event, DCPA end-use products will not be directly affected by suspension of AMVAC's DCPA technical product; all users, including AMVAC, will be able to continue sale and use of already-formulated end-use products. Although AMVAC will not be able to produce new end-use product from its suspended technical registration, any end-use product already produced at the

time the suspension becomes effective will not be subject to additional restriction from the suspension order.

With regard to pesticide residues on commodities, several of the outstanding data requirements are necessary to determine whether residues of DCPA are present and, if they are, certain commodities may be adulterated. *Supra* sections III.B.16-18. Thus, without data necessary to confirm that such residues are not present, the Agency cannot determine whether continued use results in dietary risk inconsistent with the safety standard in the FFDCA. Without data necessary to determine the risks associated with the use of DCPA, EPA cannot determine whether continued use may cause unreasonable adverse effects on the environment as defined in FIFRA Section 2(bb). 7 U.S.C. § 136(bb).

AMVAC argues that a hearing is necessary as to existing stocks provisions for two reasons. Request for Hearing at 11. The first, "to clarify the specific restrictions" imposed by the NOITS, is not further explained. *Id.* EPA maintains that the existing stocks provisions in this matter are clear and well-understood by all parties, to wit: individuals other than AMVAC that may hold stock of the suspended technical product can continue to sell, distribute, and use that registered product and anyone, including AMVAC, may continue to sell, distribute, and use end-use products formulated from the suspended product, with the caveat that AMVAC may not formulate any additional end-use products from the suspended product after the date the suspension becomes effective. *Supra* section III.C.

AMVAC's second argument, that "the express purpose of [this] hearing is to determine whether [EPA]'s determination regarding existing stocks is 'consistent with FIFRA,'" misconstrues the purpose of the statute. Request for Hearing at 11. In support of this argument, AMVAC and other Petitioners offer only statements that DCPA is a pesticide for which direct

substitutes do not exist for several uses (*e.g.*, weed control on onions), and that growers would suffer increases in production costs if they did not have access to DCPA. *Id.*at 12. As explained in section II.A of this memorandum, an applicant must show, among other things, that using a pesticide according to its specifications "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). The burden of demonstrating that a pesticide product satisfies the statutory criteria for registration is at all times on the proponents of the initial or continued registration and continues as long as the registration is in effect. 40 C.F.R. § 164.80(b). The purpose of FIFRA is not, as implied by AMVAC, to ensure that agricultural users maintain a continued supply of a specific pesticide, but rather for EPA to ensure that the pesticide's continued use will not cause unreasonable adverse effects, which requires registrants to submit necessary data so that risks can be assessed.

V. CONCLUSION

There is no dispute that AMVAC failed to comply fully with the requirements that served as a basis for the notice of intent to suspend, to wit: submitting or citing data required for EPA to complete its registration review of the pesticide active ingredient DCPA. 87 Fed. Reg. 25262, PAX 2. Numerous data requirements specified in the DCI remain unsatisfied, either due to AMVAC's failure to submit data years after the deadline for submission (in some cases years after informing EPA of its intent to comply with the DCI or, in one case, after informing EPA that it did not intend to comply), or to AMVAC's submission of repetitive requests that EPA waive the DCI data requirements after EPA previously denied similar waiver requests. *See, e.g., supra* sections III.B.11, III.B.6, III.B.3, respectively. Additionally, the existing stocks provisions of the NOITS are fully consistent with FIFRA and EPA's longstanding practice. 7 U.S.C. § 136d(a)(1); *see, e.g.*, 80 Fed. Reg. 11669, 11671. These are the only two matters permissible for

resolution by a hearing held pursuant to FIFRA Section 3(c)(2)(B)(iv). 7 U.S.C. § 136a(c)(2)(B)(iv). No other matters may be resolved and AMVAC's arguments as to the technical sufficiency of its data submissions, the time taken by EPA to review and respond to said submissions, the fact that certain data may be submitted while this hearing is pending, and EPA's rationale for requiring the submission of certain data must be dismissed by the Presiding Official. *Id.*

For these reasons, EPA requests that the Presiding Official issue an accelerated decision suspending AMVAC's registered DCPA pesticide registration, Technical Chlorthal Dimethyl, (EPA Reg. No. 5481-495) as a result of AMVAC's failure to comply fully with the data requirements of the data call-in GDCI-078701-1140, and upholding the existing stocks determinations contained in EPA's April 28, 2022 Notice of Intent to Suspend.

Respectfully submitted,

FORREST PITTMAN

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AMVAC Chemical Corporation; Grower-Shipper Association of Central California; Sunheaven Farms, LLC; J&D Produce; Ratto Bros., Inc.; and Huntington Farms, Petitioners.
Docket No. FIFRA-HQ-2022-0002

CERTIFICATE OF CONFERENCE

I hereby certify that counsel for Respondent has conferred with counsel for Petitioners, and that they are opposed to the relief sought in this **Motion for Accelerated Decision**.

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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.
Docket No. FIFRA-HQ-2022-0002

CERTIFICATE OF SERVICE

I hereby certify that the foregoing **Motion for Accelerated Decision** and the accompanying memorandum, dated June 13, 2022, were sent this day to the following parties in the manner indicated below.

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Dated June 13, 2022