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

In re FIFRA Section 3(c)(2)(B) Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration	)	**FIFRA Appeal No. 22-01**
	)	**FIFRA Appeal No. 22-02**
Docket No. FIFRA-HQ-2022-0002	)	

BRIEF OF AMICUS CURIAE CROPLIFE AMERICA IN SUPPORT OF PETITIONERS-APPELLANTS AMVAC CHEMICAL CORPORATION AND THE GROWER GROUP

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I. INTRODUCTION

CropLife America as *amicus curiae* respectfully submits this brief in support of AMVAC Chemical Corporation and the Grower Group regarding the July 1, 2022 Order on Respondent's Motion for Accelerated Decision issued by the Administrative Law Judge ("ALJ") in the above captioned cases. The ruling in the proceedings below misinterpreted a key provision of the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA") regarding the suspension of a registration. The granting of an accelerated decision—based on the misinterpretation of FIFRA's provisions for suspension of a registration—effectively nullified certain provisions of FIFRA and denied those impacted by the intended suspension of their right to a hearing. The ruling raises significant questions of due process and judicial review and has vital practical consequences for manufacturers, applicators, and distributors of pesticides in the United States as well as growers and others that use pesticides. FIFRA Section 3(c)(2)(B)(iv) (the "Suspension Clause"), provides in relevant part:

> [I]f the Administrator determines that a registrant, within the time required by the Administrator, has failed to ***take appropriate steps*** to secure the data required under this subparagraph . . . the Administrator may issue a notice of intent to suspend such registrant's registration . . . [which] shall become final . . . unless . . . a request for hearing is made . . . The only matters ***for resolution at that hearing*** shall be whether the registrant has ***failed to take the action that served as the basis for the notice of intent to suspend the registration***[.]

7 U.S.C. § 136a(c)(2)(B)(iv) (emphasis added).

The Opinion in the proceedings below construed this section to mean that there is no review of the "appropriate steps," because the ALJ was not "obliged to consider . . . whether the steps [a registrant] took to secure the data within each of [certain] time limits were 'appropriate.'" Dkt. 28, "Opinion," at 20. But this is the precise question that FIFRA calls upon the ALJ to resolve, and the refusal to do so was in error.

The Opinion interprets the language to mean that the Office of Pesticide Programs ("OPP"), the principal office within EPA administering FIFRA, has the sole and final say of determining whether the steps a registrant took were "appropriate." It reasons that "such evaluations and determinations are better made by" the OPP, and that it is "more suitable" for OPP to "evaluate questions of whether [a registrant] has taken appropriate interim steps" than the ALJ. *Id.* at 21 n.24. Such a reading, however, would make the language in the Suspension Clause providing for a hearing superfluous.

The Opinion also places significant weight on the fact that the EPA was facing a registration review deadline in October of 2022. It reasons that a failure to suspend the registration would "inevitably result in the Agency being in violation of law," and would "reward" the registrant. *Id.* at 31. As discussed below neither assertion is correct, and, thus, cannot support the decision. As this Board and the courts have recognized, EPA has failed to meet similar deadlines under environmental statutes and there are recognized remedies to address the delay. Providing an end run around FIFRA's process for suspension of a registration, however, is not one of them. For these reasons, CropLife America, as *amicus curiae*, respectfully submits that the decision below should be reversed and the Board should provide instruction regarding the proper interpretation of the suspension provisions.[1]

II. INTERESTS OF THE AMICUS CURIAE

CropLife America, established in 1933, is the national trade association for the plant science industry, representing developers, manufacturers, formulators, and distributors of

[1] Both the registrant, AMVAC, and the intervenors, The Grower-Shipper Association of Central California, J&D Produce, Ratto Bros., Inc., and Huntington Farms (collectively, the "Grower Group") do not oppose CropLife America filing an amicus brief. The Pesticides and Toxic Substances Law Office takes no position regarding the amicus brief.

pesticides and other plant science solutions for agriculture and pest management. CropLife America's member companies produce, sell, and distribute pesticides, including herbicides, insecticides, and fungicides, which farmers use to provide consumers with abundant food and fiber. CropLife America is committed to safe and responsible use of the industry's products.

CropLife America's members are deeply invested in discovery and development of new pesticide products and product uses. They are intimately familiar with the comprehensive federal regulation of pesticides under FIFRA. CropLife America's member companies spend, on average, $286 million and 11.3 years on research, development, and registration on pesticide products that reach the marketplace.[2] CropLife America's member companies have a keen interest in FIFRA's legal framework, particularly—as it applies here—to the registration and registration review of its members' products and any suspension of such registrations. The issues here reach well beyond a single product, impacting an entire industry. CropLife America respectfully submits this brief to help the Board understand the regulatory framework of FIFRA and explain why the decision below is unsupportable both as a matter of law and policy.

III. BACKGROUND

A. REGULATORY BACKGROUND

FIFRA is a "comprehensive regulatory statute," *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984), governing the sale, use, and labeling of "pesticides." FIFRA makes it unlawful to "distribute or sell to any person any pesticide that is not registered" under the statute. 7 U.S.C. § 136a(a). A FIFRA registration is a federal license to sell the product. *See Reckitt*

[2] *See* Phillips McDougal, "The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010-2014," A Consultancy Study for CropLife International, CropLife America and the European Crop Protection Association 3-4 (March 2016), https://croplife.org/wp-content/uploads/2016/04/Cost-of-CP-report-FINAL.pdf.

Benckiser, Inc. v. Jackson, 762 F. Supp. 2d 34, 36 (D.D.C. 2011) ("A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used.") (citing 7 U.S.C. § 136a(a), (c)-(e)). FIFRA's registration process requires EPA to evaluate risks to human health and the environment[3] and requires registrants to provide substantial scientific data to support the safety and health effects of a pesticide. *See* 7 U.S.C. §§ 136a(c)(1)(F) & (c)(2)(A) (governing information required to support registration).

Congress provided that EPA review the registration of currently registered products at least once every 15 years to confirm whether a pesticide continues to satisfy FIFRA's registration standards. 7 U.S.C. § 136a(g); 40 C.F.R. § 155.40 *et seq.* (registration review regulations). This process involves a review of the applicable science under public notice and comment procedures. *See* 40 C.F.R. § 155.50. The initial review after registration is to be completed "not later than the later of—(I) October 1, 2022; or (II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered." 7 U.S.C. § 136a(g)(1)(A)(iii). FIFRA also states that "[n]o registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d" of FIFRA. 7 U.S.C. § 136a(g)(1)(A)(v).

As part of this review process, if EPA determines that additional data are required EPA may send a Data Call-In notice ("DCI") to the registrant(s) to provide additional information. 7 U.S.C. § 136a(c)(2)(B)(i); 40 C.F.R. § 155.48. The Administrator "shall permit sufficient time for applicants to obtain such additional information." 7 U.S.C. § 136a (c)(2)(A). "Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking

[3] *See* EPA Pesticide Registration Manual: Introduction, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-introduction.

appropriate steps to secure the additional data that are required." 7 U.S.C. § 136a(c)(2)(B)(ii). If a "registrant fails to comply with this clause," the "Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv)." *Id.*

EPA may establish or modify data needs for individual pesticide chemicals. 40 C.F.R. § 158.30. Registrants generally are "encouraged to discuss a data waiver request with the Agency before developing and submitting supporting data, information, or other materials," and "[t]he Agency will review each waiver request and subsequently inform the applicant in writing of its decision." 40 C.F.R. §§ 158.45(b)-(c).

B. THE PROCEEDINGS BELOW

The record below established that EPA initiated its initial registration review of dimethyl tetrachloroterephthalate ("DCPA"), and as part of that review, on January 31, 2013, EPA issued a DCI to AMVAC under 7 U.S.C. § 136a(c)(2)(B). Dkt. 28 at 4-5. The DCI requested various types of data and established timeframes for submitting the data, ranging from 9-36 months. *Id.* at 5. AMVAC timely responded to the DCI within 90 days, "indicating that it planned to comply with the request by developing data, submitting existing data, upgrading existing studies, deleting uses for which data are required, and requesting waivers of certain data." *Id.* at 6. Thereafter, a long series of communications commenced between AMVAC and EPA regarding submission of certain data, adjustments of certain data protocols, and waiver requests by AMVAC and responses to those requests from EPA. *See* Dkt. 1 at 8-29 (summarizing correspondence).

After several years of these discussions, EPA issued a letter on October 26, 2020, noting that certain of the data requested in the 2013 DCI remained outstanding. Dkt. 28 at 6. Then, on April 28, 2022, EPA issued its Notice of Intent to Suspend Registration ("NOITS"), asserting that AMVAC has not complied with 20 of the outstanding data requirements originally called for by

the DCI. *See* Dkt. 28 at 6; Dkt. 1. Concurrent with the NOITS, EPA also provided AMVAC with memos regarding review of previously submitted studies, at times calling for supplementation of data but without classifying the studies as "unacceptable" or "rejected." *See, e.g.*, McMahon AMVAC Statement, Dkt. 15, Ex. 3, ¶ 23. AMVAC, the sole registrant of DCPA, and the Grower Group, timely objected to EPA's NOITS and, consistent with the statute, requested a hearing. Dkt. 28 at 1. EPA filed a motion for accelerated decision shortly thereafter, which the ALJ granted on July 1, 2022. *Id.* at 2. AMVAC and the Grower Group timely appealed.[4]

IV. ARGUMENT

A. STANDARD OF REVIEW

The standard of review for the Board is *de novo*. *See* 40 C.F.R. § 164.91(b) (decision rendered under accelerated review "shall have the same force and effect as an initial decision"); *In Re: Bayer Cropscience LP and Nichino America, Inc.*, 17 E.A.D. 228, 2016 WL 4125892, at *25 (EAB 2016) ("The Board reviews an ALJ's findings of fact and conclusions of law in the Initial Decision on a *de novo* basis.") (citations ommitted).

B. THE ANALYSIS BELOW WAS PREMISED ON A FAULTY STATUTORY INTERPRETATION

The Opinion's faulty interpretation of the Suspension Clause impacted the entire analysis, leading to an outcome that is unsupported by either law or policy. Moreover, the interpretation denies the registrants' rights, including a hearing before suspension, that Congress clearly intended to provide.

[4] The Notice of Exceptions and Appeal Brief of AMVAC was docketed as FIFRA 22-01. The Notice of Exceptions and Appeal Brief of Grower Group was docketed as FIFRA 22-02. CropLife America is filing this amicus brief in both dockets at the direction of the Clerk of the Board.

1. The FIFRA Suspension Provisions Must be Read in Context

As with any statutory provision, Section 3(c)(2)(B)(iv), must be read within the context of the overall statutory scheme. *See In Re: U.S. Army, Fort Wainwright Central Heating & Power Plant*, 11 E.A.D. 126, 2003 WL 21500416, at *13 (EAB 2003) ("it is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in their overall statutory scheme")(internal quotation marks omitted). The applicable registration review provisions provide that "[t]he Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review." 7 U.S.C. § 136a(g)(2). The suspension provision under 7 U.S.C. § 136a(c)(2)(B), in turn, provides the following rubric for requiring the data:

First, section (c)(2)(B)(i) ("clause i") provides that if the Administrator determines that additional data are required to maintain an existing registration of a pesticide, EPA must notify registrants. *Second*, section (c)(2)(B)(ii) ("clause ii") provides that within 90 days of receiving such a notification, a registrant must "provide evidence" that it is "taking appropriate steps" to "secure the additional data" required by the Administrator, and that several registrants may share the cost of developing such data. If the registrant fails to comply with this clause—that is, it fails to provide evidence within 90 days that it is taking appropriate steps to secure the additional data, or in case of several registrants, notify the Administrator that they have agreed to do so—the Administrator shall issue a NOITS in accordance with the procedures described in clause (iv). *Third*, section (c)(2)(B)(iii) ("clause iii") provides that if the several registrants cannot agree on the terms of jointly developing the data, they are to begin arbitration proceedings. If they fail to do so, the Administrator shall, once again, issue a NOITS in accordance with the procedures described in clause (iv). *Finally*, the Suspension Clause—clause (iv)—referenced above in clauses (ii) and (iii), provides in relevant part:

> Notwithstanding any other provision of this subchapter, ***if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph***, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, ***the Administrator may issue a notice of intent to suspend such registrant's registration*** . . . [which] . . . shall become final . . . unless . . . a request for hearing is made . . . If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing ***shall be 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 for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter[.]

7 U.S.C. § 136a(c)(2)(B)(ii) (emphasis added).

Thus, under the Suspension Clause the Administrator may issue a NOITS based on one of three possible bases: "if the Administrator determines that a registrant, within the time required by the Administrator, has failed":

1. to take appropriate steps to secure the data required under this subparagraph,

2. to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or

3. to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph.

These three bases in this clause, including taking "appropriate steps to secure data," and participating in arbitration proceedings, correspond to those listed in the immediately preceding clauses (ii) – (iii), which themselves cross-reference clause (iv).

The registrant may then request a hearing, and "[t]he only matters for resolution at that hearing shall be whether the registrant has failed to take ***the action*** that served as ***the basis*** for the

notice of intent to suspend the registration." That "basis" must necessarily be one of the three listed in the previous paragraph, and bases 2 and 3 (regarding arbitration and cost sharing) have no relevance to these proceedings. So the "action" that served as the "basis" in this case must be the purported failure by the registrant "to take appropriate steps to secure the data required under this subparagraph" within the time required by the Administrator. The "only matters for resolution at that hearing," therefore are whether the registrant "within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph[.]"

2. The Opinion's Reading of the Statutory Language Is Unsupported by the Plain Text or the Statutory Structure of FIFRA

The Opinion's reading of this statutory language was incorrect. The Opinion looks to the NOITS itself—not the Suspension Clause—to determine the "action" on which it was based. Dkt. 28 at 20. It focuses on the following language of the NOITS: "*Following the registrant's failure to submit [certain] data* or to take other appropriate steps to secure the required data, *the agency is unable to fully evaluate the risks associated with DCPA . . . The failure of the registrant to comply with [certain] . . . data requirements . . . is a basis for suspension*[.]" *Id.* (emphasis in original).[5] From this language, the Opinion concludes that "[t]hus, in this case the 'action' AMVAC is alleged to have 'failed to take' is to submit, *at all, to date,* certain data requested in the 2013 DCI." *Id.* This results in statements like:

- "I find no merit to AMVAC's argument that I am obligated to consider . . . whether the steps AMVAC took to secure the data within each of [certain] time limits were 'appropriate'" (*Id.* at 20);
- "whether AMVAC 'acted reasonably' is largely beside the point in this proceeding" (*Id.* at 25);

[5] Even if looking at the NOITS itself was proper, the Opinion simply ignored the portion of the above-quoted language in the NOITS stating "or to take other appropriate steps to secure the required data."

- "AMVAC failed to take the action that served as the basis for the NOITS because it has failed to produce the data required by the DCI in the time required by the Agency." (*Id.* at 26);

- "the factual issue is whether AMVAC failed to complete the submissions required by the DCI, not whether it acted reasonably or appropriately under the circumstances" (*Id.* at 27);

- "Each of the datasets requested in the DCI presents potential bases for the NOITS," and "AMVAC's failure to comply with any *one* of these bases is sufficient cause for suspension regardless of its compliance with any other data requirement." (*Id.* at 31).

Contrary to the statements above, however, whether AMVAC took the "appropriate steps" to secure the data in the timeframe required by the Administrator is not "largely beside the point in this proceeding." Rather, for the reasons explained in the previous section, it was ***the*** question that the ALJ was tasked with deciding under FIFRA.[6]

3. The Opinion's Analysis is Unsupported by the Other Provisions of FIFRA or its Legislative History

Aside from the statutory text, the Opinion relies on two other factors in support of its interpretation of the Suspension Clause. Neither holds water.

First, it notes that "[a]side from abiding by the plain language of the statute, limiting the scope of this proceeding in this manner is consistent with the 75-day time limit on this proceeding . . . If Congress intended a more in-depth assessment of the 'appropriateness' . . . it would not have required that this whole proceeding begin and end in less than three months." Dkt. 28 at 20-21.

[6] The Opinion's emphasis on the binary question (i.e., was the data was provided or not) also ignores that fact that the statute focuses on "appropriate steps to ***secure*** the data" (not "provide" the data, or "submit" the data). The Opinion reasons that to adopt a reading that a registrant "need only prove that it took 'appropriate steps' *towards providing* the required data . . . is akin to inviting registrants to spend an interminable amount of time *attempting* to provide data without actually providing it." *Id.* at 21. But, in addition to ignoring the word "secure" in the statute, this again sidesteps the very question that the ALJ is called upon to decide. While there may be times when a registrant did not take "appropriate steps to secure the data," whether AMVAC did so in this case was the question to resolve at the FIFRA-mandated hearing.

But analyzing the 75-day timeframe in light of other FIFRA provisions shows that this deadline was more than sufficient to assess the appropriateness of a registrant's steps.

For example, under 7 U.S.C. § 136d(c) (pertaining to suspension of registrations due to an "imminent hazard," not at issue here), if the Administrator wishes to suspend registration, a registrant may request a hearing, which "shall commence within five days of the receipt of the request for such hearing," and the presiding officer must then issue his or her recommendation ten days after the hearing. Viewed in this light, the hearing deadlines, whether 5 days or 75 days, are designed not to signal the breadth of issues to be addressed, but to afford a registrant the prompt opportunity to present its case in the face of pending suspension.[7]

Second, the Opinion asserts that the legislative history supports its interpretation of the relevant language. It does not. As the Opinion recognizes, the Senate's initial version of this provision called for the Administrator to cancel the registration without a hearing if a registrant failed to take appropriate steps to secure the registration. The House's version called for a hearing under FIFRA sections 6(b) and 6(d). Dkt. 28 at 22; 123 Cong. Rec. S13087-13103, 13100 (daily ed. July 29, 1977)). In the reconciliation of these bills, the conference committee provided for a hearing process but added "the only matters for resolution" language and the 75-day hearing

[7] Other examples are found throughout FIFRA. For example, under 7 U.S.C. § 136d(d), which concerns cancellation hearings but is expressly incorporated into 7 U.S.C. § 136a(c)(2)(B)(4), the hearing examiner "shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing," which then "shall report in writing . . . within 60 days after such referral on these questions of scientific fact." Also under 7 U.S.C. § 136d(b), if the Administrator wishes to cancel a registration, he must provide "an analysis of such impact on the agricultural economy" to the Secretary of Agriculture who then has 30 days to provide comments. Certainly if Congress believed that 60 days was sufficient for the National Academy of Sciences to provide answers to scientific issues presented at a hearing and 30 days was sufficient for the Secretary of Agriculture to analyze the impact of a cancellation on the entire agricultural economy, the 75 days provided under the Suspension Clause is sufficient time to determine whether a registrant took "appropriate steps" to secure required data.

provision. Dkt. 28 at 22. This shows that Congress afforded registrants a hearing mechanism to protect their rights, not to limit them.

The Opinion asserts that the conference committee's changes were notable "because they focus the inquiry in this proceeding on whether data have in fact been timely produced." Dkt. 28 at 23. But looking at the summary of the major provisions of the conference committee bill printed into the record shows that this was not the focus. Rather, the focus was to:

> Establish procedures governing the generation of data that may be required for the maintenance of existing registrations of a pesticide, including provision for requiring all registrants of the pesticide ***to take appropriate steps to secure the necessary additional data***, authority for cost-sharing arrangements by which the necessary data can be developed and submitted jointly by the registrants to avoid the waste involved in duplicative testing, and provisions for settling disputes over cost-sharing arrangements by binding arbitration.

124 Cong. Rec. 29756, 29758 (Sept. 18, 1978). So, contrary to the assertion below, the focus of Congress was on a registrant taking "appropriate steps to secure" the data.

4. Two Specific Conclusions Below Are Particularly Concerning

While the Opinion's entire analysis was impacted by the flawed reading of the statutory text, two sections merit particular attention:

a. The Opinion's deferral to EPA in this context is unwarranted.

First, footnote 24 of the Opinion states that determinations and evaluations of the appropriate steps are better left to EPA,[8] because FIFRA grants the Administrator "discretion to assess the appropriateness of a registrant's actions prior to issuing a NOITS," which "makes sense" given EPA's "management of such tasks as setting deadlines for data submissions," etc. Dkt. 28 at 21 n.24. While the ALJ did not "formally defer to [EPA] in the same sense that a federal court

[8] Technically, the OPP within EPA, conducting DCPA's FIFRA-mandated registration review. Dkt. 28 at 21 n.24.

gives legal deference to agency decision-making," she nevertheless recognized that the rationale for deference "is particularly strong when the [EPA] is evaluating scientific data within its technical expertise," *id.* (citation omitted), and therefore found it "more suitable for the science and technical experts within OPP than it is for this Tribunal to evaluate questions of whether AMVAC has taken appropriate interim steps to provide necessary data[.]" *Id.*

The Opinion correctly determines that "Chevron deference," as may be used by *federal courts* when deferring to agency statutory interpretations, does not apply here. Dkt. 28 at 21 n.24; Dkt. 20 at 14 n.11; *In Re: Consent Agreements and Proposed Final Orders For Animal Feeding Operations*, 2006 WL 478143, at *9 n.21 (EAB 2006) ("Under *Chevron*, an agency's interpretation of a statute is entitled to deference if the statute is silent or ambiguous with respect to the specific issue, and the interpretation proffered by the agency is reasonable. This doctrine, however, is not applicable to cases before the Board.").[9] However, while the discretion of whether to issue a NOITS lies with the Administrator, the footnote implies that the Administrator's own determination of whether the steps a registrant took were "appropriate" is the final say on the matter, and the ALJ should defer to the Administrator regarding whether the steps are appropriate. Such an interpretation would make the statutory language providing for the right to a hearing superfluous. In other words, there would then simply be no "matters for resolution at [a] hearing," and EPA would always be entitled to an accelerated decision by virtue of the Administrator determining that a registrant has failed to take what the Administrator believes to be the "appropriate steps." Such a reading would strip registrants of their due process rights and is simply incorrect. *See Reckitt Benckiser, Inc.*, 762 F. Supp. 2d at 43 ("To interpret FIFRA to give EPA

[9] *See also, e.g.*, *In Re: Mobil Oil Corporation*, 5 E.A.D. 490, 1994 WL 544260, at *12 n.30 (EAB 1994) ("Because the Board serves as the final decisionmaker for the Agency, the concepts of Chevron and Skidmore deference do not apply to its deliberations.").

[certain] authority not only renders Section 6 superfluous; it also allows EPA to avoid the rigorous cancellation process Congress provided for in the statute.").

Perhaps for these reasons the ALJ did not technically defer to the OPP. Nevertheless, she "recognized as a general principle" that "[t]he rationale for deference is particularly strong when the [EPA] is evaluating scientific data within its technical expertise." Dkt. 28 at 21 n.24. This "general principle," however, does not apply here.

In support of this "general principle," the Opinion cites *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1000 (D.C. Cir. 2008), but the issue there was over whether "introgression" (the "entry or introduction of a gene from one gene complex into another") was harmful or beneficial to a certain species of trout. *Id.* at 996. The scientific literature on the question differed, and the court ruled that in those circumstances, it would defer to EPA on setting the level of introgression for purposes of classifying trout as threatened (or not) under the Endangered Species Act. *Id.* at 1000. But deferring to EPA on setting introgression levels in the face of differing scientific opinions—as in *Kempthorn*—is quite different than deferring to its opinion of whether a FIFRA registrant took "appropriate" steps—as here. The former is a question of EPA "evaluating scientific data within its technical expertise." *Id.* The latter is a decision that is within the ability of the ALJ or this Board.

Moreover such a decision would circumvent Congress' intent regarding the due process for a cancellation. Suspensions may be lifted under the Suspension Clause when the Administrator "determines that the registration has complied fully" with the necessary requirements. However, as seen in this case it can take over a year for EPA to review a study once submitted, *see e.g.*, Freedlander AMVAC Statement, Dkt. 15, Ex. 1, at ¶ 12, and multiple years for EPA after receiving a study to notify the registrant that EPA has determined that the study is acceptable or not

acceptable, *id at* ¶¶ 21, 32, 126. EPA could use this delay to effectively cancel a registration because the suspension would remain in place for many years. An extended suspension of the active ingredient would impact others including growers. *See generally* Dkt. 3 at 3-7. EPA cannot bypass cancellation proceeding and "effect[ively] cancel" a registration without following the cancellation proceeding provided in the statute. *Reckitt Benckiser, Inc.*, 762 F. Supp. 2d at 43.

b. The Opinion's statements regarding EPA's timeline of review is a non-sequitur and should have made no impact on the determination.

The Opinion concludes its analysis by stating that "if DCPA's registration was permitted to remain active while the review process was on-going, it would inevitably result in the Agency being in violation of law," because of EPA's registration review deadline of October 2022. Dkt. 28 at 31. To that end, it would "reward AMVAC by allowing it to maintain its registration in effect past the statutory deadline, having obtained the benefit of delayed compliance costs." *Id.* In other words, the ALJ believed that without a suspension of registration, EPA would be unable to meet its October 2022 deadline, and the fallout from that missed deadline must be borne by registrants and users of the pesticide product. FIFRA does not support such an interpretation.

First, 7 U.S.C. § 136a(g)(1)(5) provides that "[n]o registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title." Section 136d mandates that the Administrator provide an impact report to the Secretary of Agriculture and provides for opportunities for a full hearing and other safeguards for registrants. In drafting 7 U.S.C. § 136a(g)(1)(5), therefore, Congress expressly provided that regardless of EPA's registration review process, it cannot simply cancel a registration (no matter how close it was to its statutory review deadline) without following the requirements affording protections to registrants. The same reasoning applies to suspension provisions, as otherwise, EPA could create an end-run around 7 U.S.C. § 136a(g)(1)(5), simply by

suspending thousands of registrations *en masse* due to its impending statutory review deadline, without having to comply with the cancellation provisions of FIFRA. Such an outcome would be contrary to Congress' intent. *See supra* at pages 13-14 and *Reckitt Benckiser, Inc.*, 762 F. Supp. 2d at 43. Moreover it is of particular concern in a situation such as this one where EPA rejected certain submitted studies or waiver requests concurrent with issuing the NOITS. McMahon AMVAC Statement, Dkt. 15, Ex. 3, ¶¶ 23, 26; Freedlander AMVAC Statement, Dkt. 15, Ex. 1, ¶¶ 44, 63-67.

Second, the burden of EPA in complying with its Congressionally-mandated registration review deadlines cannot be shifted to the registrants. Otherwise EPA could, for example, take no action with regard to a waiver request by a registrant, and then simply suspend it registration because EPA's own statutory review deadline is forthcoming. Moreover, in this case, EPA itself has not indicated that a failure to provide data required by the DCI will prevent it from meeting the October 2022 deadline, but only that it will need to use "conservative assumptions" in its analysis. *See* JX 21.

Third, missing Congressionally-imposed deadlines is not a unique situation for EPA, and there are mechanisms to address the instances when it does so. For example, in the context of the Clean Air Act, the Ninth Circuit noted that "[t]he EPA is no stranger to consent decrees that set deadlines after it fails to timely promulgate designations." *Sierra Club v. North Dakota*, 868 F.3d 1062, 1068 (9th Cir. 2017). In *Sierra Club,* the court noted that by the time EPA's deadline for designating national ambient air quality standards under the Clean Air Act had expired—the agency "had designated only 29 areas, leaving undesignated more than 3,000 counties throughout the country," leading an environmental organization to file suit. *Id.* at 1065. In affirming the consent decree that was ultimately entered, whereby EPA agreed to meet certain new timelines,

the court noted that the Clean Air Act "does not prescribe a remedy for default," and "the appropriate remedy in a 'deadline' case such as this is to require [the] EPA to issue designations pursuant to a schedule, not to mandate that [the] EPA issue any particular designation." *Id.* at 1068. This case shows that approaches exist to address EPA's compliance with its Congressionally-mandated deadlines other than shifting the burden to registrants and users.

Finally, the cases cited in the Opinion, Dkt. 28 at 31, do not stand for the proposition that a burden is properly shifted to regulated entities to ensure Congressional compliance by the agency regulating them. Rather, they either say that an agency cannot act in a way that exceeds the scope of its Congressional authority, or support the point in the previous paragraph, that if an agency does so, avenues of judicial recourse are available to aggrieved parties. *See, e.g.*, *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485 (2021) (the statute on which the CDC relied to extend eviction moratorium did not give it authority to do so); *Texas v. United States*, 555 F. Supp. 3d 351, 363 (S.D. Tex. 2021) (Department of Homeland Security "may not instruct its officers to enforce [an immigration] statute in a manner contrary to the law itself."); *Ctr. for Food Safety v. Hamburg*, 954 F. Supp. 2d 965, 971 (N.D. Cal. 2013) (while failure to comply with statutory deadline constituted a "failure to act," as the Opinion notes that was in the context of a suit brought by a party against the FDA, showing that avenues of recourse exist to ensure agency's compliance with statutory deadlines); *Am. Lung Ass'n v. Browner*, 884 F. Supp. 345, 347 (D. Ariz. 1994) (aggrieved party has opportunities for recourse when agency misses statutory deadline, in the context of Clean Air Act).

C. UNDER THE CORRECT STATUTORY READING, THERE ARE MULTIPLE DISPUTED ISSUES OF MATERIAL FACTS, REQUIRING REVERSAL OF THE ACCELERATED DECISION

As discussed above, the Opinion's improper reading of the Suspension Clause impacts the entire analysis. Under the correct reading of that clause, it is clear that an accelerated decision in

favor of EPA was in error. Under the standards for an accelerated decision, similar to the standards for summary judgement under Fed. R. Civ. P. 56, the decision below can be upheld only if "no genuine issue of material fact exists," 40 C.F.R. § 22.20(a), and thus only if "no reasonable decisionmaker" could resolve any material issue of fact in the registrant's favor, viewing the facts in the light most favorable to the registrant. *In Re: BWX Technologies*, 9 E.A.D. 61, 2000 WL 365958, at *12 (E.A.B. 2000).

When analyzed under the proper reading of FIFRA, there are multiple disputed issues of material facts regarding whether AMVAC took the "appropriate steps" to secure the data required by EPA. While CropLife America will not go through all of the exhibits submitted by the parties below, it generally observes that there is evidence in the record showing that:

- AMVAC's responses were "typical of how registrants address data call-ins," and that the communications with EPA were "typical of what registrants routinely experience" (Gur AMVAC Statement, Dkt. 15, Ex. 7, ¶ 43);
- EPA rejected certain studies or waiver requests concurrently with issuing the NOITS, failing to put AMVAC on notice that its waiver requests or data were insufficient (McMahon AMVAC Statement, Dkt. 15, Ex. 3, ¶¶ 23, 26; Freedlander AMVAC Statement, Dkt. 15, Ex. 1, ¶¶ 44, 63-67);
- EPA at times waited several years before expressing any concerns with previously-submitted data (Freedlander AMVAC Statement, Dkt. 15, Ex. 1, ¶¶ 32, 126); and
- Even when EPA had drafted a response, it did not provide it to AMVAC for several years (*Id*. at ¶ 53).

When this evidence is viewed in light most favorable to AMVAC, and against FIFRA's statutory requirements that, for example—"the Administrator shall permit sufficient time for applicants to obtain such additional information," 7 U.S.C. § 136a(c)(2)(A); that the Administrator shall review materials received "as expeditiously as possible," 7 U.S.C. § 136a(c)(3)(A); and that registrants are "encouraged to discuss a data waiver request with the Agency before developing and submitting supporting data, information, or other materials," 40 C.F.R. § 158.45(b)—there are

multiple disputed issues of material fact demonstrated by the record below regarding whether AMVAC "within the time required by the Administrator, has failed to take appropriate steps to secure the data."

V. CONCLUSION

For the reasons above, CropLife America, as *amicus curiae*, respectfully submits that the decision below should be reversed with directions on the appropriate standard.

Dated: July 28, 2022

Respectfully submitted,

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STATEMENT OF COMPLAINCE WITH WORD LIMITATIONS

The undersigned certifies that the foregoing **Brief of *Amicus Curiae* CropLife America in Support of Petitioners-Appellants AMVAC Chemical Corporation and the Grower Group**, excluding the cover page, table of contents, table of authorities, signature block, this statement of compliance, and the certificate of service, contains fewer than 7,000 words. It contains 6,202 words, as counted by Microsoft Word, including textboxes, footnotes, and endnotes.

/s/ Sara Beth Watson
Sara Beth Watson

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on July 28, 2022, the foregoing **Brief of *Amicus Curiae* CropLife America in Support of Petitioners-Appellants AMVAC Chemical Corporation and the Grower Group** was filed with the Environmental Appeals Board (www.EPA.gov/EAB) and was served on the following parties by the methods indicated below.

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