

AMVAC

Exhibit 1

Additional Examples of Failure to Apply Correct Standard for Grant of Summary Motion

Section of Order	Discussion/Type of Error
<p>The Order finds that AMVAC’s conduct with respect to this study of toxicity to fish was not reasonable. Order at 25 (noting that “AMVAC’s ‘reasonableness’ argument has no merit” even if considered). Order at 25.</p>	<p>EPA invited AMVAC to undertake the precise strategy AMVAC undertook. Order at 9, discussing EPA’s suggestion in JX 66 to conduct a specified study on daphnids, which AMVAC then did. <i>See</i> Freedlander (AMVAC) Statement ¶¶ 56-62. AMVAC told EPA it would follow EPA’s direction in 2018, <i>id.</i> ¶ 58, and reported the results of EPA’s requested study in 2020. <i>Id.</i> ¶ 61. AMVAC thereafter never heard back from EPA until April of 2022, concurrently with the NOITS. <i>Id.</i> ¶ 63. Troublingly, when the Order should merely recognize the existence of a genuine factual dispute and deny EPA’s motion as to this study, it instead characterizes AMVAC’s conduct as “doubling down” on a prior waiver request, evoking a reckless gambler rather than a registrant following agency direction.</p> <p><u>Type of Error:</u> Ignoring existence of genuine factual dispute. Reasonable fact finder could determine AMVAC acted appropriately by following EPA’s direction.</p>
<p>The Order refers to EPA’s October 2020 letter as “formally advis[ing]” AMVAC that the waivers had been denied, suggesting that AMVAC should have known its “double or nothing” bet (as the Order characterizes a second waiver request) had failed. Order at 25.</p>	<p>EPA’s October 2020 letter, JX 21, referred only to an EPA DER dated March 21, 2014 (footnote 5 within the October 2020 letter, which AMVAC had not received until 2017). Freedlander (AMVAC) Statement ¶ 53. AMVAC had already informed EPA that it would perform EPA’s recommended daphnid test to further support the waiver in February 2018. JX 67. There is therefore a genuine dispute regarding whether EPA’s October 2020 letter conveyed any finality concerning EPA’s position, because that letter ignored the 2018 correspondence advising EPA that AMVAC would perform the daphnid test as EPA suggested. AMVAC then submitted the results of the tests, JX 22, and did not hear back until after the notice. McMahon (AMVAC) Statement ¶ 26.</p> <p><u>Type of Error:</u> Ignoring existence of genuine factual dispute. Reasonable fact finder could determine EPA did not “formally” or otherwise advise AMVAC that waiver denial was final.</p>

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<p>The Order states that AMVAC, after submitting the additional data in December of 2020, JX 22, “[knew] that [the waiver request] may or may not be found acceptable” and “did nothing” until the NOITS was issued. Order at 25.</p>	<p>EPA first notified AMVAC that several waivers were accepted in April of 2022, proving that EPA was still actively considering them as of that date. The Order fails to mention that this was also when EPA first responded to the December 2020 waiver. So AMVAC’s conduct with respect to the request was completely typical – registrants never know for sure if EPA will grant a request, and registrants typically do not take any action pending a response from EPA on the waiver; doing so would make little sense. Gur (AMVAC) ¶ 37. It is inappropriate to resolve a motion for accelerated decision solely by deferring to EPA’s technical assessment of whether a waiver request was so lacking as to not constitute an appropriate step, if that even is the basis for the conclusion in the Order, for the reasons discussed in AMVAC’s Appeal Brief in Section IV.A.3.</p> <p><u>Type of Error:</u> Failure to specify if discussion is material. To the extent it is material, it would be improper to conclude conduct was not “appropriate” based solely on agency assertion to that effect when registrant conduct was typical per expert testimony.</p>
<p>“Moreover, even if I were to consider the appropriateness of AMVAC’s actions under the circumstances . . . waiting until it received the Agency’s Outstanding Data Letter in 2020 to begin [the DCPA Fish Early Life Stage] studies involving the other necessary fish species is not appropriate.” Order at 24</p>	<p>The Order first concedes that the ALJ cannot determine why AMVAC did not initiate the additional two studies until after receipt of the Outstanding Data Letter in 2020. A hearing would allow this determination, after consideration of all the facts and circumstances. Based on the current record – most notably, the text of the Outstanding Data Letter in 2020, Joint Exhibit (“JX”) 21 (which stated that data could still be provided in a “timely” fashion), and that EPA in fact accepted waiver requests and other studies even up to concurrently with the issuance of the suspension notice in 2022, <i>e.g.</i>, JX 69.</p> <p><u>Type of Error:</u> Ignoring existence of genuine factual dispute. A reasonable fact finder could determine that AMVAC acted appropriately by initiating a study immediately after being told that data could still be provided in a “timely” fashion (and ultimately submitting that data shortly after the NOITS was issued).</p>

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<p>The Order asserts that it is “undisputed that AMVAC did not produce acceptable data” with respect to the DCPA mysid study and therefore its registration may be suspended. Order at 25.</p>	<p>This is genuinely disputed; EPA first asserted that a study submitted in 2014 was unacceptable eight years after receiving it, as discussed in detail in AMVAC’s Appeal Brief in Section IV.A.2, and AMVAC immediately contacted the laboratory for an assessment of EPA’s evaluation. AMVAC does not concede that the study does not fulfill the data requirement. Freedlander (AMVAC) Statement ¶¶ 18-24. The fact that EPA did not communicate with AMVAC about this study in any way in the eight years between when it was submitted and the issuance of the notice precludes any finding, at this stage of this proceeding, that AMVAC’s actions were inappropriate.</p> <p><u>Type of Error(s):</u> Ignoring existence of genuine factual dispute. Improper deference to EPA. Improper focus of appropriate steps inquiry. Based on EPA’s complete non-response for the ensuing eight years, until the NOITS was issued, the correct question is whether AMVAC’s submittal of the study was an “appropriate step.”</p>
<p>The Order asserts that “[i]f AMVAC was uncertain about the necessity of some of the TPA ecotoxicity studies, it was incumbent upon AMVAC to clarify with the Agency, not make an erroneous assumption based on silence.” Order at 27.</p>	<p>AMVAC provided expert testimony that AMVAC’s course of conduct was typical. Gur (AMVAC) Statement ¶¶ 37-42 (discussing that it is not uncommon to wait “months or even years” for a response to a waiver request and that registrants often clarify waivers if they are initially denied). The Order nonetheless finds that because EPA informed AMVAC of “its approaching June 2021 deadline” to perform risk assessment, AMVAC had an obligation to proactively reach out to the Agency to check on the status of its waiver requests. Order at 28. But EPA’s communication – JX 21 – clearly informed AMVAC that EPA would proceed to complete risk assessment regardless of whether any particular study had been submitted or any particular waiver accepted – EPA would just have to use “conservative assumptions”</p> <p><u>Type of Error:</u> Improper inference drawn in favor of EPA. The October 2020 letter does support a conclusion that AMVAC thereafter had a new obligation to affirmatively clarify with EPA the status of waivers pending before the Agency. Doing so would be inconsistent with DCI response practice generally. <i>See</i> Gur (AMVAC) Statement ¶¶ 37-42.</p>

Section of Order	Discussion/Type of Error
<p>The Order’s conclusion that AMVAC’s conduct with respect to the “Diatom TPA data” was a proper basis for the suspension notice. (“I am not convinced by AMVAC’s arguments concerning the amount of time it took EPA to respond to waivers; whether these data are actually needed for EPA’s risk assessments; or whether AMVAC acted reasonably and appropriately. AMVAC Hearing Request ¶¶ 11, 324; Response at 22.”) Order at 28.</p>	<p>Here the Order fails to provide any detail concerning why AMVAC’s specific arguments that it took appropriate steps were rejected. These are fact-centric inquiries being decided against AMVAC in the absence of a hearing. Of course, the Order grounds its conclusion on its narrow legal standard, which is improper for the reasons discussed in Sections IV.A.1-3 of AMVAC’s Appeal Brief. But here the Order does not at all address AMVAC’s substantive arguments, which it at least does to some degree concerning the other studies discussed in the Order at pp. 24-31.</p> <p><u>Type of Error:</u> Failure to provide findings with sufficient detail to confirm if summary judgment principles were properly applied.</p> <p>A review of the facts concerning the marine diatom (a type of algae) study confirms that AMVAC’s conduct should be judged to be appropriate. This is because the marine diatom was one of several species which might have required testing under Guideline 850.4500 for the degradate of DCPA, TPA. AMVAC followed EPA’s suggestion to perform a test in daphnids, and provided that data in 2020. Freedlander (AMVAC) Statement ¶ 82. EPA in April of 2022, though it denied the waiver request for the marine diatom, actually approved waiver requests for other species of algae under the same test Guideline which otherwise would have been required. JX 69. Thus, OPP is drawing a line between “appropriate” waiver requests and “inappropriate” waiver requests based only on the ultimate results of its review, which were not provided until after the NOITS was issued. Clearly AMVAC’s waiver requests were not frivolous if they were still actively being granted in April of 2022. AMVAC is entitled to a hearing to contest EPA’s position that its approach was so lacking in substance as to not be an “appropriate step.”</p> <p><u>Type of Error:</u> Ignoring existence of genuine factual dispute; improper deference.</p>

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<p>The Order’s failure to address the inference that EPA may not have reviewed substantive waiver correspondence concerning the <i>Leptocheirus</i> chronic sediment toxicity data, and other issues related to the analysis of this data requirement. Order at 28-30.</p>	<p>The Order refers to AMVAC’s assertion that there is evidence that EPA did not review one of AMVAC’s waiver requests in connection with this study in any correspondence that would be expected to have referred to it, and therefore EPA may not have reviewed it at all. AMVAC had contended that multiple EPA documents, including the final EPA rejection of the waiver request in April of 2022 concurrent with the NOITS, had all failed to refer to this document. <i>See</i> JX 21, JX 69, and EPA’s fact witness testimony, none of which refer to JX 76. But the Order fails to explain why this episode does not present a genuine issue of material fact.</p> <p><u>Type of Error:</u> Ignoring existence of genuine factual dispute; failure to recognize dispute as material possibly even under narrow standard applied. It would be troubling if OPP’s “appropriate steps” analysis (to which the Order improperly defers) could be accepted even if OPP had ignored or misplaced substantive correspondence from AMVAC. EPA may contest that this information was relevant or substantive, creating a genuine fact issue, but it does not appear to contest that it never reviewed it. May EPA still suspend a registration even if a registrant establishes that EPA never reviewed relevant correspondence?</p>
<p>The Order resolves a genuine dispute <i>against</i> AMVAC when it states that “the failure to conduct the [Leptocheirus] test over the years is overwhelmingly attributable solely [sic] to the choices and decisions AMVAC alone made; completing the study was never beyond its control.” Order at 30.</p>	<p>There is a contested inference as to whether it would have been possible to complete the special study originally called for. EPA acknowledged that the study proved challenging to perform and offered an alternate on that basis. JX 74 at 2 (June 27, 2016). EPA’s more recent correspondence (April 2022) only states that “several studies” had subsequently been accepted by EPA, which “should limit previously identified issues.” JX 69 at 18-19. But EPA still offered the alternative that had been offered as a result of the issues identified. JX 1 at 26. Based on the extensive challenges identified with this study, a genuine dispute exists concerning whether “completing the study was never beyond its control.”</p> <p><u>Type of Error(s):</u> Ignoring existence of genuine factual dispute. Improper deference to EPA.</p>

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<p>The apparent finding that “when the parties held a telephonic meeting, EPA made it clear to AMVAC that the <i>Leptocheirus</i> sediment study was still outstanding and not waived[.]” Order at 30.</p>	<p>The relevant post-meeting notes (JX 35 at 1-2 (annotated by EPA after the meeting)) include a statement by EPA that a “Response to Amvac [is] pending” concerning whether SS-1072 would be waived if an alternate study was completed. <i>Id.</i> This appears directly below a reference to the prior communication (JX 74, the June 27, 2016) indicating it would not be waived.</p> <p><u>Type of Error(s):</u> Ignoring existence of genuine factual dispute. A reasonable inference, which creates a genuine fact issue, is that EPA’s action item was to re-confirm its position and “respon[d] to Amvac,” not that it was, by sharing this document, reconfirming that position. JX 35 at 2.</p>
<p>Footnote 27 in the Order’s discussion of the <i>Leptocheirus</i> study.</p>	<p>This improperly resolves against AMVAC the question of whether EPA may informally add new requirements to a DCI, something AMVAC contended EPA improperly attempted to do with an “alternate” study EPA said AMVAC could perform after acknowledging that labs were having trouble performing the “special study” EPA had actually requested in the DCI. The Order asserts incorrectly that FIFRA does not require EPA to include data requirements in a DCI. Order at 29 n.27 (asserting that FIFRA only requires EPA to “notify” registrants of needed data, not include them in a DCI). But why would the DCI process exist at all, if EPA may simply “notify” registrants of a need for data at any time? All of the support provided for the Order’s conclusion in this regard is inapposite: (1) 7 U.S.C. § 136a(c)(2)(B)(i)’s reference to “notification” is, as a plain textual matter, a reference to notification <i>via</i> a formal DCI; (2) 40 C.F.R. § 155.50(c) refers to a method by which EPA may request data from registrants (or the public) relevant to registration review but responses (including from the registrant) are <i>optional</i> (“Any person may submit data or information in response”); (3) 40 C.F.R. § 155.53 refers only to formal DCIs and the “optional” information request process in 40 C.F.R. § 155.50(c); and (4) the fact that the agency has discretion concerning whether or not it issues a formal DCI, <i>see</i> 7 U.S.C. § 136a(c)(2)(B)(i); 40 C.F.R. § 155.48 (“The Agency <i>may</i> issue a Data Call–In notice under FIFRA section 3(c)(2)(B) . . . ”) (emphasis added) does not establish that it has discretion to issue mandatory informal requests.</p> <p><u>Type of Error(s):</u> Reaching incorrect legal conclusion.</p>