Douglass, James

From: Turnbough, Anne <AnneT@amvac.com>
Sent: Wednesday, February 21, 2024 7:18 PM

To: Douglass, James

Cc: Britton, Cathryn; Bloom, Jill; Kiely, Timothy; McMahon, Niamh; Mirabella, Brooks; Jonynas, Ann; Perez

Ovilla, Oscar

Subject: Amvac Response DCPA 2/21/24 **Attachments:** AMVAC_response_DCPA_Feb21.pdf

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Dear James & Team,

Upon consultation with our senior management, AMVAC is responding to EPA's most recent email in the timeframe agreed to with Tim Kiely. In an effort to provide a succinct response, we incorporated answers to your summary statements from your email summarizing EPA's outreach efforts. You will note that while we agree with several key points, we continue to request clarification on some statements. Overall, AMVAC believes in the viability of our proposed mitigation strategy where we can continue to deliver a key tool to growers while removing the overall risk concern. Amvac understands that this document may be added to the public record in its entirety. AMVAC continues to be open to further discussions to find a collaborative path forward.

Sincerely,

Anne

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In May 2023 EPA published an occupational risk assessment of DCPA and in a companion document EPA stressed the need for feasible risk mitigation for occupational handlers. AMVAC has therefore been in continuous discussions focusing on mitigations with EPA to maintain the key grower supported uses of DCPA. The registered product Dacthal Flowable is a soil applied preemergent herbicide, for use on key specialty vegetables, namely brassica, onions and radish. EPA has supported that DCPA has significant benefits for cultivation of those crops or certain cultivation practices of those crops as published in their BEAD document found in the following link (regulations.gov docket: EPA-HQ-OPP-2011-0374-0081)

AMVAC's public comments in the same docket proposed both comprehensive and user validated feasible risk mitigation restrictions and acceptable rate reductions for key crops eliminating the overlying human health risk of concern (MOE > 100) to occupational handlers and post application workers. AMVAC encourages EPA to review these proposed mitigations again as a sound scientific pathway to retain key uses for growers with restrictions while removing the human health risk concern.

Several discussions to educate the EPA on the common agrochemical practices for key crops resulted in AMVAC proposing to limit the label to maintain uses over the top of brassica transplants and soil applied direct seeded brassica, direct seeded onions and direct seeded radish. The mitigation proposes use of the current application techniques (broadcast, chemigation and banded applications). Engagement with the end users on acceptable reduced rates and utilization of daily limit amount for mixers and loaders and applicators were based on achievement of an MOE > 100. Extending Reentry intervals (REIs) to a feasible field practice was proposed to protect post application workers. AMVAC has additionally proposed to EPA that an RUP designation for Dacthal Flowable would aid in recordkeeping and enforceability.

AMVAC has provided information to EPA via the original public comments and EPA requested technical responses on the most efficacious use of DCPA within the variable cultivation practices for brassica and onions. The mitigations proposed by AMVAC below are considered feasible by growers contacted during extensive and ongoing stakeholder outreach. Understanding some of EPA concerns, AMVAC has researched 3rd party data sources including CA PUR reports validating that growers are operating within or close to those restrictions already. AMVAC references CA data specifically due to CA being a key state for the crops of interest and the most thorough data set to review application data. AMVAC is still expecting a response from EPA on the risk calculations for REIs post application to *brassica* transplants. Please advise on the status of this response.

AMVAC also submitted a protocol as agreed with EPA for a modified CTA study to further define the gestational NOAEL by testing additional dose levels between the NOAEL at 0.1 and the LOAEL at 1 mg/kg/day. AMVAC is ready to initiate this study post finalization of mitigation discussions with EPA.

Specifically, AMVAC has proposed to EPA the following activity-based REI restrictions for Dacthal Flowable:

- For post application activities such as scouting do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of >10 days
- For post application activities such as hand setting irrigation, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of > 21 days
- For post application activities such as weeding, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of > 21 days

For occupational handlers AMVAC proposes the following daily amounts handled:

• Mixer/loaders may only handle 19.2 gallons of product (115.2 lb AI) a day to prepare application spray. Applicators may only handle 15 gallons of product (90 lb AI) a day for applications.

RESPONSE TO EPA EMAIL 2-15-24 POST TECHNICAL DISCUSSIONS BETWEEN AMVAC AND EPA

AMVAC received the EPA comments below on February 15th, 2024, after a technical call discussing EPA's risk assessment calculations and mitigations proposed by the Agency in late 2023. Both AMVAC and EPA are aligned that risk is mitigated and feasible/enforceable except in 2 areas where AMVAC considers risk is successfully mitigated. However, the restrictions proposed by AMVAC are deemed unenforceable by EPA if placed on the product label as proposed above. AMVAC prepared the following response to this email to be transparent on where we agree with EPA but also where we do not align on the feasibility as supported by key stakeholders.

Note: EPA comments are in black font and AMVAC response in blue italics:

• Reached out to states including ID, WA, OR, CA, AZ, FL, and MI, through AAPCO, state extension specialists, state agencies/departments, and academia.

General DCPA use, direct-seeding vs. transplants

- DCPA was banned in MI 20 years ago due to detection in groundwater, and surveyed brassica and onion growers claimed they would not use it again even if state law changed.
 - DCPA is not registered in MI and likely not following discussions and mitigated uses therefore feedback from the state of MI is irrelevant. There is not a good agronomic fit in MI for DCPA.
- In OR and ID, DCPA is still applied but its overall use has declined. Now that drip irrigation is being used more than furrow irrigation, usage may increase in OR. Use rates and costs are high for DCPA; where growers can use something else, they do.
 - AMVAC agrees that the use has declined over the last 2 years as supply of the chemical was impacted. Users had no choice but to revert to alternative solutions despite the negative impacts economically. Feedback from recent users indicates that alternatives have been less effective than DCPA. AMVAC has already communicated with EPA that acceptance of proposed restrictions has been vetted among the grower community. AMVAC do not understand the relevance of the comment on irrigation type in OR. Growers continue to emphasis with AMVAC the negative economic impacts of hand weeding as an alternative to DCPA.
- In FL, leafy cole crops are mostly direct-seeded and head/stem cole crops (broccoli, brussels sprouts, cauliflower, etc) are mostly transplanted
 - AMVAC anticipates this is accurate and will reach out to FFVA, the specialty crop group in FL, to confirm.
- In AZ and CA, broccoli is primarily direct seeded.
 - o From our research and grower outreach this is an inaccurate assessment. Growers choose their planting method based on their specific market and economic needs and indicate a breakdown of 50% direct seeded and 50% transplant for broccoli cultivation.
- Most growers in Florida treat with DCPA 2-3 days before transplanting; depending on how those applications are made, transplanters could be exposed at transplant time.

- For efficacious use of the product, DCPA should only be applied once all soil disturbing activities (such as transplanting) cease.
- Growers in all other states are treating transplanted crops immediately after transplant, suggesting that they may rely on over-the-top application.
 - AMVAC agree with this statement.

Comments on acreage limitations, compliance, commercial applicators

- For directly seeded crops like onions, growers treat as many acres as possible at the same time so much smaller daily acreage application limits would be difficult. Across states, planting of directly-seeded onions and cole crops happens quickly and broadly, e.g., growers can seed 60-90 acres per day for onions and 40-50 acres per day for cole crops.
 - AMVAC agrees-for Brassica daily application acre allowances proposed by AMVAC are up to 40 acres at 50% banded configuration and up to 66 acres at a 30% banded configuration. Therefore, AMVAC's proposal is completely feasible for brassica growers to adhere to the proposed daily application rates as they are aligned with daily planting rates.
- Extension specialists indicated it would be tough to comply with acreage limitations for growers
 who directly seed their crops; there would be substantial costs incurred with this dramatic shift
 in current agronomic practices.
 - Discussions with large growers of direct seeded onions have indicated they would be forced to use alternatives due to label restrictions as it would be uneconomical. We do not hear the same concerns from direct seeded brassica growers.
- Average field sizes for cole crops in CA are generally below 20A but can be as high as 80A.
 - AMVAC agrees that it is correct for direct seeded and transplant brassica cultivation in CA and also in AZ.
- Generally, growers stagger the planting of transplanted crops (to a maximum of ~20 acres per
 day) to make hand harvesting and sale of these fresh market crops feasible (so that harvests can
 occur sequentially rather than all at once).
 - AMVAC agrees that this practice does occur, and this is additionally true for direct seeded crops. This practice substantiates AMVAC's proposed mitigations. AMVAC reminds EPA that transplanting equipment typically can only plant 8 acres a day of brassica transplants which is significantly lower than the broadcast acreage allowance for brassica transplants of 13.3 acres a day. Transplanting is the rate limiting step in brassica cultivation not limiting daily allowances of DCPA for occupational handlers.
- Contacts in California and Oregon, where some existing pesticide labels include acreage limitations, expressed few reservations both that growers would comply and that enforcement could occur successfully.
 - We request EPA clarify this statement as its meaning is unclear to AMVAC.
- Outside of California, contacts at state lead agencies indicated that it could be challenging to enforce this type of restriction without a specific record-keeping requirement on labels. Under the WPS, records of pesticide applications must be kept, but few state agencies require filing of such records with the state and most states cannot track grower applications of pesticides in real time.
 - AMVAC is receptive to putting a record keeping requirement on label. This was proposed by OPMP (USDA) in recent discussions. AMVAC has vast experience with product stewardship and education programs with multiple states and believe we could replicate

a similar program with DCPA. Product registration at a state level can be limited to less than 15 states, further minimizing state obligations to enforce new label language.

- In Arizona and California, many DCPA applications are made by commercial applicators. Oregon growers generally make their own DCPA applications.
 - For CA/AZ we agree this is the case. As noted above AMVAC supports designating
 Dacthal Flowable as a Restricted Use Product (RUP) to restrict application to certified
 applicators only and aid record keeping and enforceability.
- Several extension specialists noted that acreage limitations could pose a particular issue for commercial applicators, who may service multiple growers on a particular day.
 - As previously discussed with EPA CA PUR (Pesticide Use Reporting) data did not indicate this but AMVAC will approach County Agricultural Commissioner offices to confirm this further.
- Commercial applicators may have relatively limited manpower to split up the mixing/loading
 responsibilities so applications may be made by the same people (EPA's assessment
 methodology generally assumes that handlers mixing/loading pesticides are different than the
 handlers who apply pesticides, except for applications with hand-held equipment).
 - AMVAC will propose label language that makes this distinction as accepted on other approved pesticide labels.

Occupational post-application; scouting, record-keeping

- An extended REI will likely not work for transplanted crops, since they are heavily managed directly after transplantation (must reenter fields within the first week or 10 days for scouting, particularly for insects, and irrigation).
 - AMVAC have proposed a 10-day scouting REI. AMVAC have not yet received a technical response from EPA on acceptability of reaching an MOE of greater than 100 with such an REI.
- Notably, if damaging amounts of insect or weeds are observed, that could lead to other postapp activities in the transplanted field, like weeding or insecticide spraying.
 - AMVAC have proposed an REI of 21 days for weeding which has been validated as acceptable by growers. A concern for subsequent pesticide applications has not been raised until now and there is no EPA SOP that AMVAC can find on risk calculations for setting an REI for subsequent pesticide applications. Upon consulting the WPS implementation manual for early entry for such applications no references were found other than pesticide application doesn't seem to be defined as hand labor in WPS. AMVAC would anticipate that applicators will be utilizing the PPE required for that product.
- Growers who do their own scouting probably do not keep records of those activities, but
 growers who rely on crop consultants for pest scouting would have records collected by the
 consultants. (None of the queried contacts were aware of state requirements for pest scouting
 records.
 - REIs are a key label element for risk mitigation and is enforceable label language.
 AMVAC will add mandatory requirements for posted signs for reentry as acceptable on other pesticide labels for real time visibility of REI status to protect workers.
- California has extensive and comprehensive pesticide data reporting requirements. Of the remaining states, only Arizona requires that commercial applicators submit records of all of their pesticide applications

 Per above AMVAC agrees these states have strong use reporting processes but that does limit other states from adopting enforceable stewardship programs. This has been acceptable for other chemistries.

Banding

- California producers of processing onions do not band DCPA applications, as their wide beds and tight row spacing make it impractical.
 - This statement is limited as processing onion cultivation is not representative of all onion applications methods in CA. It occurs on wide beds to facilitate mechanical harvesting and so broadcast applications are exclusively used. However, cultivation of other onion types are more mixed and both broadcast and banded applications do occur. Many counties in CA require banded applications per the current label.
- Sources conveyed that the term "banded application" needs to be defined more thoroughly: in CA, crops other than onions are grown in ~40 inch wide beds, and DCPA is already applied in ~20 inch strips down the middle.
 - AMVAC notes this is a standard configuration and correlates to a 50% banded application configuration. But AMVAC would also like to note that other configurations do occur and it not the only one used in CA or AZ.

Pesticide alternatives to DCPA

- Experts in Michigan (where DCPA was banned in 2003), Oregon, Washington, and Arizona identified alternatives to DCPA
 - AMVAC has provided a complete analysis with stakeholder input and responded to EPA on DCPA alternates in our public comments (regulations.gov: EPA-HQ-OPP-2011-0374-0098). We redirect EPA to that document for more details on specific concerns summarized here per AI:
- bensulide concerns with inferior weed control, limited weed spectrum and requires supplemental hand weeding; reduces brassica stand in cold wet conditions
- oxyfluorfen concerns with crop injury in less-than-ideal conditions; no tolerance on lettuce so concerning if used in proximity to lettuce; poor grass weed control
- dimethenamid-P concerns with crop safety (onions)
- ethofumesate concerns with crop safety and plant back restrictions
- flumioxazin (Chateau) Stakeholders have not raised this alternative with AMVAC, so no assessment has been completed
- Pyroxasulfone (Zidua) not registered for use on brassica
- S-metolachlor concerns with weed control spectrum
- clomazone not registered in CA/AZ
- napropamide concerns with brassica crop safety (root inhibition); injury to follow on crops
- pendimethalin concerns with residual and long crop rotations; poorer weed control spectrum than DCPA, crop safety
- treflan concerns with residual and long crop rotations; volatile and requires incorporation; poorer weed control spectrum than DCPA
- and tank mixes of ethalfluralin, ethofumesate, or pendimethalin with glyphosate
- Alternatives vary by crop and direct seeded vs. transplant. Some states require state
 registrations in addition to federal registrations, and the state registrations of some of these
 prospective alternatives are not now on the books.

0	All end use products require state registration in all 50 states. Napropamide, pendimethalin, clomazone and oxyfluorfen currently have crop and/or states registration gaps.