Dicamba OTT New Use on DT-Cotton and DT-Soybeans: Bayer Briefing for Touchpoint 1

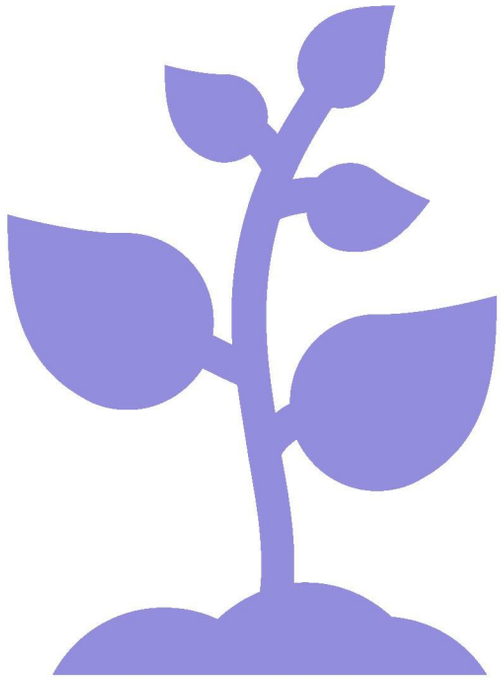
May 12, 2025

Outline

- Introductions
- Human Health Risk Assessment
- EFED Assessment
- Next Steps
- Questions

Human Health Risk Assessment

- Toxicity
  - Toxicology database considered complete for assessing potential exposures from the proposed uses
  - No new toxicological studies have been submitted since the previous risk assessment
  - No changes to the endpoints or safety factors outlined in the previous risk assessment have been made
- Chemistry/Dietary
  - Robust chemistry dataset supports established tolerance levels for soybean and cotton
  - Unrefined acute and refined chronic dietary (food plus drinking water) assessments were conducted and resulted in no risks of concern.
- Occupational/Residential Exposure
  - No residential exposures from the proposed uses; aggregate recommendations remain the same
  - Occupational handler and post-application exposures anticipated
  - No dermal hazard identified; only handler inhalation exposure and risk assessment; no risks of concern identified
- Aggregate Exposure
  - No risks of concern identified
- Non-Occupational/Bystander Exposure
  - No risks of concern identified for potential exposure via spray drift nor from potential volatilization from the field



EFED Risk Assessment

Scope: All Uses on Proposed Label (DT-soybean, DT-Cotton)

Analysis Plan for Dicamba OTT: Evaluation of HS, VSAP and Residual Risks

FIFRA Risk Assessment

- Leverage dicamba OTT environmental fate and toxicity data from the previous assessment of dicamba OTT

Herbicide Strategy

- All listed plants
- All obligates (effects to plant-based PPHD)
- All CH (plant portion) and Generalists

VSAP

- Certain plants (not covered by HS analysis)
- **Volatility**
- Certain animals
  - Direct effects
  - Effects to PPHD and effects to CHs (same mitigation as generalists in HS)

Residual Risk

- All animals not in VSAP
  - **Direct effects are the primary focus**
  - Effects to PPHD and effects to CHs (same mitigations as in HS) plus **Volatility**

Effects Determination

- Individual level effects
- Likely at No J/AM based upon mitigations (informed by HS, VSAP, remaining risk)

FIFRA Risk Assessment - Overall Conclusions

- Based on the proposed labels, dicamba OTT use preliminarily poses potential risks to individuals of the following taxa:
  - On-field risk concerns to mammals, birds (terrestrial-phase amphibians and reptiles), and terrestrial invertebrates
  - On and off-field risk concerns for terrestrial and wetland plants through drift and runoff exposure
- Dicamba spray drift and runoff are of concern to terrestrial and wetland plants
- Volatility exposure concerns

Identify potential for population-level impacts

- Categories based on mean EECs

Exposure route	Habitat	Population-level impact	
		Listed plants	Listed generalist animals
Spray drift	All	15 ft	15 ft
Runoff	Terrestrial	Not Likely (0)	Not Likely (0)
	Wetland (non-flow)	Medium (6)	Low (3)
	Wetland (flow)	Low (3)	Not Likely (0)
	Aquatic	Not Likely (0)	Not Likely (0)

Identify where runoff mitigation applies

- Listed plants + obligate animals
  - 6 points for listed plants in non-flowing wetlands (PULAs 5 & 6)
  - 3 points for listed plants in flowing wetlands (PULAs 7 & 8)
  - 3 points for generalists in non-flowing wetlands (PULA 9)
- If 3 points on the label, then could potentially change NMFS LAA calls to NLAA

Species Count by UDL

PULA	Soybean	Cotton
5	13	13
6	10	4
7	12	6
8	7	7
9	6	3
Total unique species core maps	47	
Core maps in development	3 complete 22 in progress 22 not started	

VSAP and Residual Risk

- Population level impact concerns for VSAP listed terrestrial and wetland plants
- Animal VSAP species not expected to be on cotton or soybean, so no concerns
- For residual risk, EPA did not predict the likelihood of future jeopardy for any on-field listed animals that are not in VSAP
- Spray drift and runoff mitigations match those identified by HS for generalists
- Volatility mitigations will be on the general label

Dicamba OTT Volatility Toxicity Data

- Population Based Endpoint
  - 25% reduction in plant height for soybean (most sensitive tested species)
  - 38% Visual Signs of Injury represents the median of %VSI to 25% height for all available direct spray and volatility soybean studies that measured height and VSI
- Studies on volatility exposure to soybeans
  - Field based volatility exposure study (Zaccaro-Gruener etal 2023)
    - Using range **6.5 to 8.5 ng/m^3** (represents uncertainty in the endpoint selection)
  - Soybean is most sensitive tested species but many other species show symptoms in landscape
    - Plant uptake of atmospheric dicamba may have a limiting step (uptake saturation limit)

Drivers of Volatility Exposure

Temperature	• Dicamba volatilization increases with an increase in temperature.
pH	• Volatilization potential is increased when pH is decreased, a significant decrease in pH can occur in common tank mixes. • Volatility Reducing Agents (VRAs) can be used to increase/stabilize the pH in tanks.
Landscape Level Applications	• Growers locally near each other applying dicamba around the same time in warm conditions has the potential for large volatilization events.
Humidity	• Increased humidity may also drive down volatilization, but the impact is likely less than temperature. • Humidity could contribute to higher toxicity responses.

Dicamba OTT Volatility Exposure Data

- Characterization of humidome data from 2020 assessment
  - Volatility tended to increase with increases in temperature
  - Volatility tended to increase with decreases in formulation pH
  - Volatility was not impacted by changes in relative humidity
  - Tank mix components can have an impact on volatility (underlying reasons unclear)
- ~52 field studies reported in 2020 assessment
  - Most studies are DGA mixed with GLY (n = ~26)
  - Most Studies before and after 2018 utilized a VRA
- One new humidome and two new field volatility studies were evaluated for this assessment (soybean, DGA + GLY with a VRA)

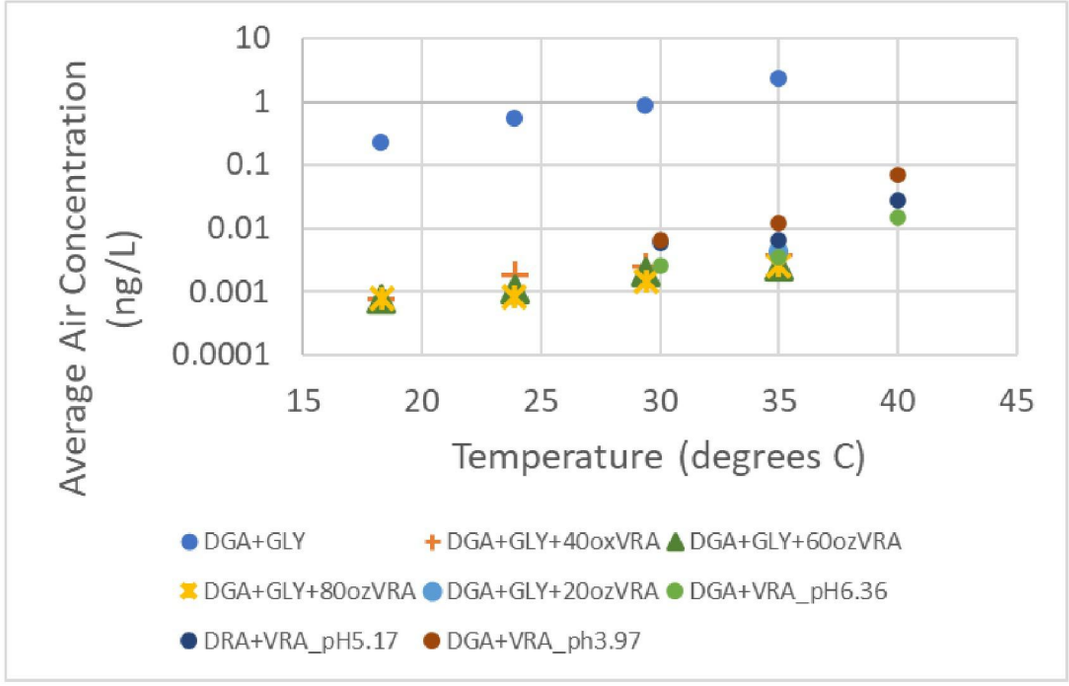
Dicamba Volatility with Increasing Temperature

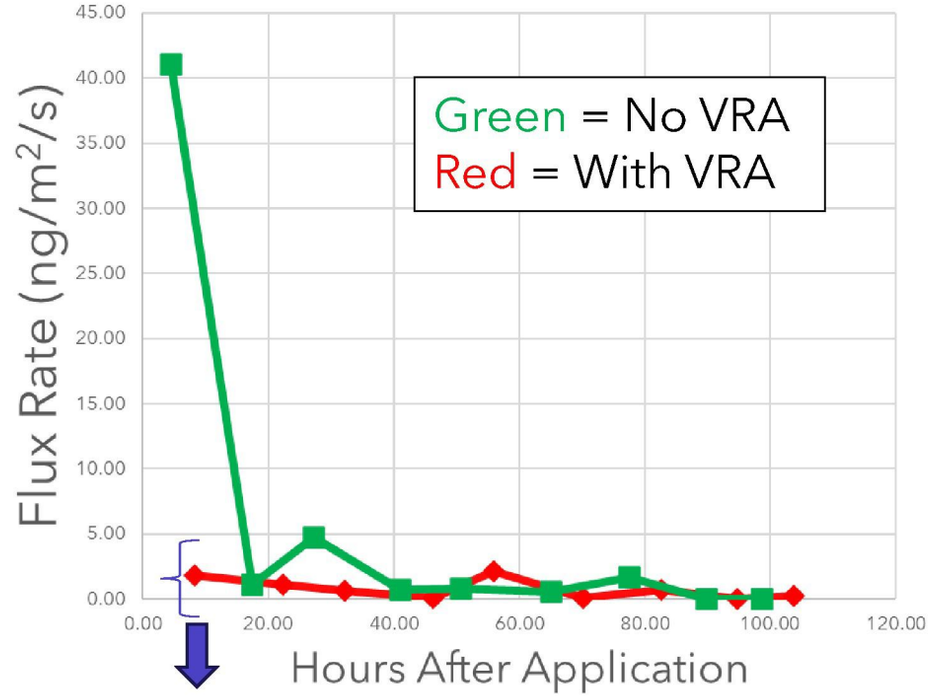
- Avoiding application when air temperatures are favorable to volatility would decrease the conditions that may have led to dicamba-related non-target plant incidents
- If the temperature were 75°F, the scaled distance to effect would be 0 m.
- Humidome study linear regression shows air concentrations increase with increasing temperature and decrease with increasing pH
- Meaningful increase above 85˚

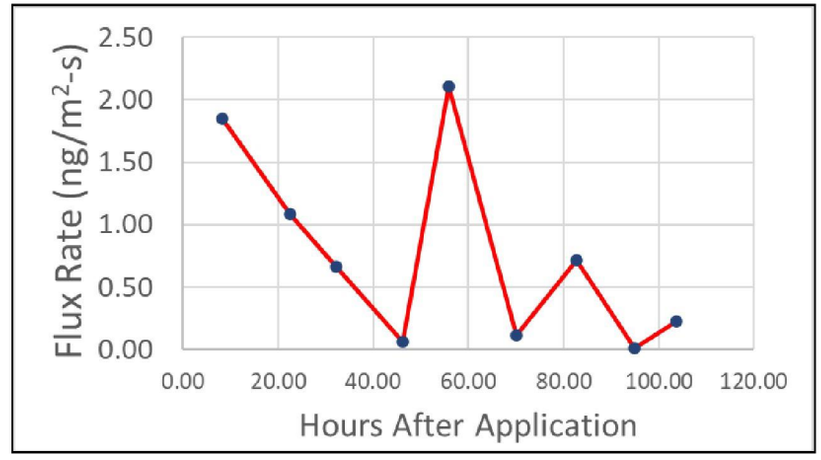
˚F	Air concentration increase from 75˚ F
80	1.5x
85	2x
90	3x
95	3x
100	5x

VRA Influence on Dicamba Volatility

- VRA is effective at reducing volatility, in the lab and the field
- Effectiveness seems to peak and flat line at a ~1:1 ratio (e.g. 22 fl oz product/A to 20 fl oz VRA/A)
- There are dicamba emissions when using a VRA





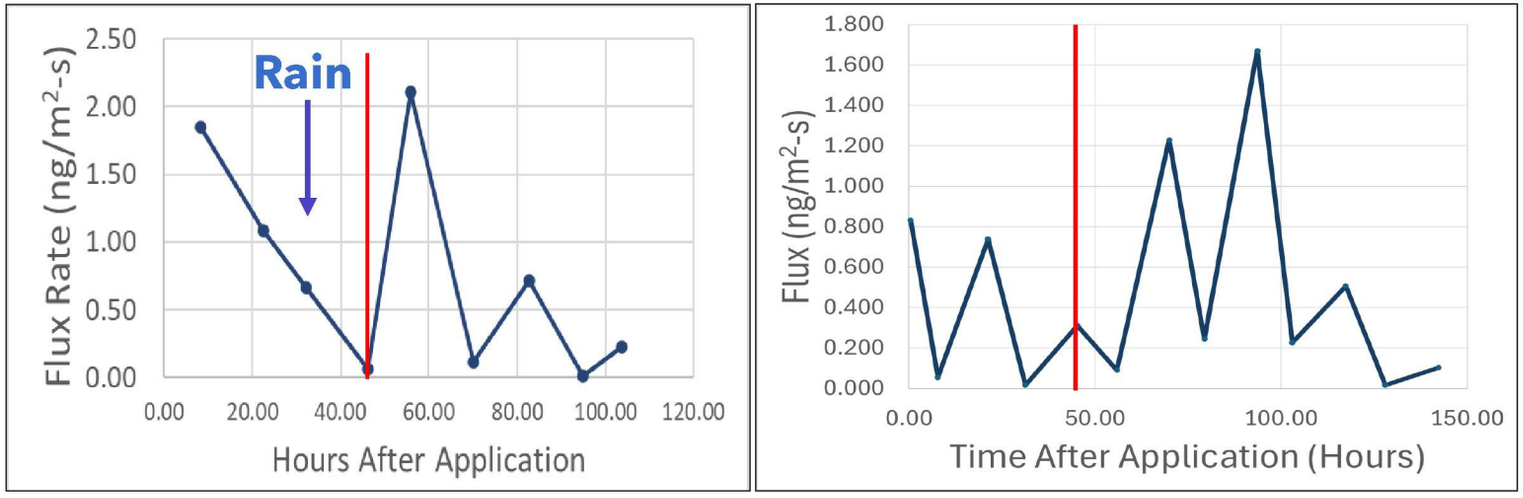


*Zoom into red line

Timing of Flux Profile

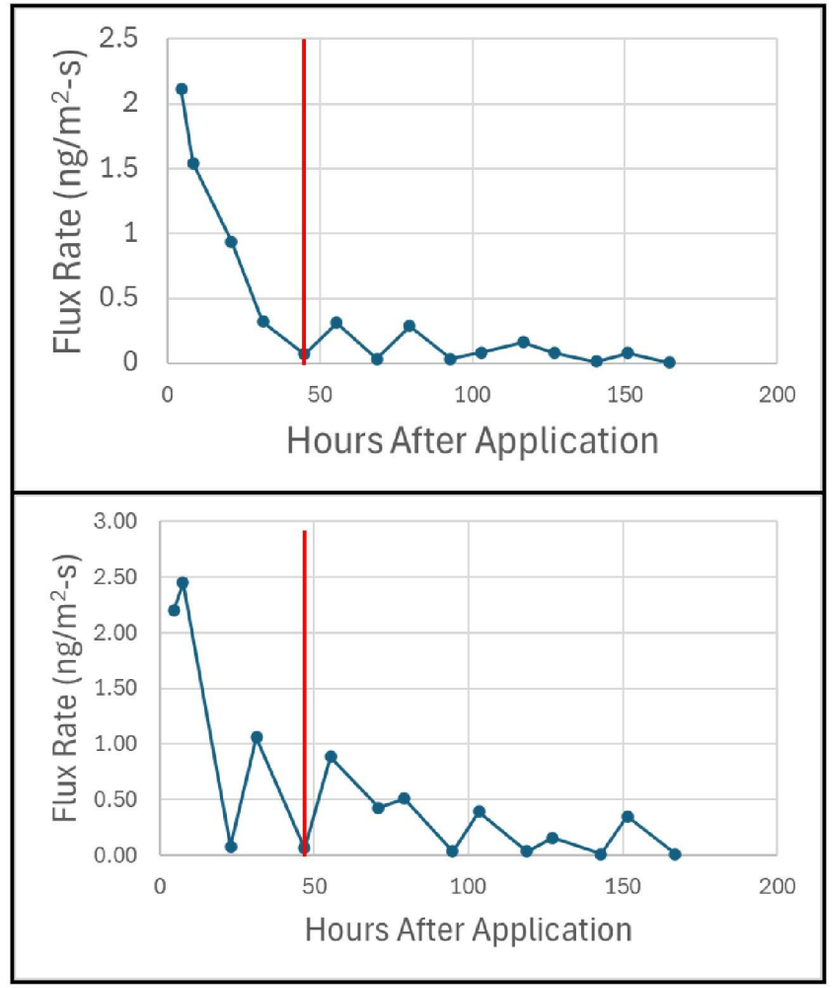
- All submitted field studies show dicamba emissions after 48-hrs
- Most studies show majority of the volatility in the first 48 hours
- There are examples of high flux rates after 48hrs

90˚ F **95˚ F**



New Studies

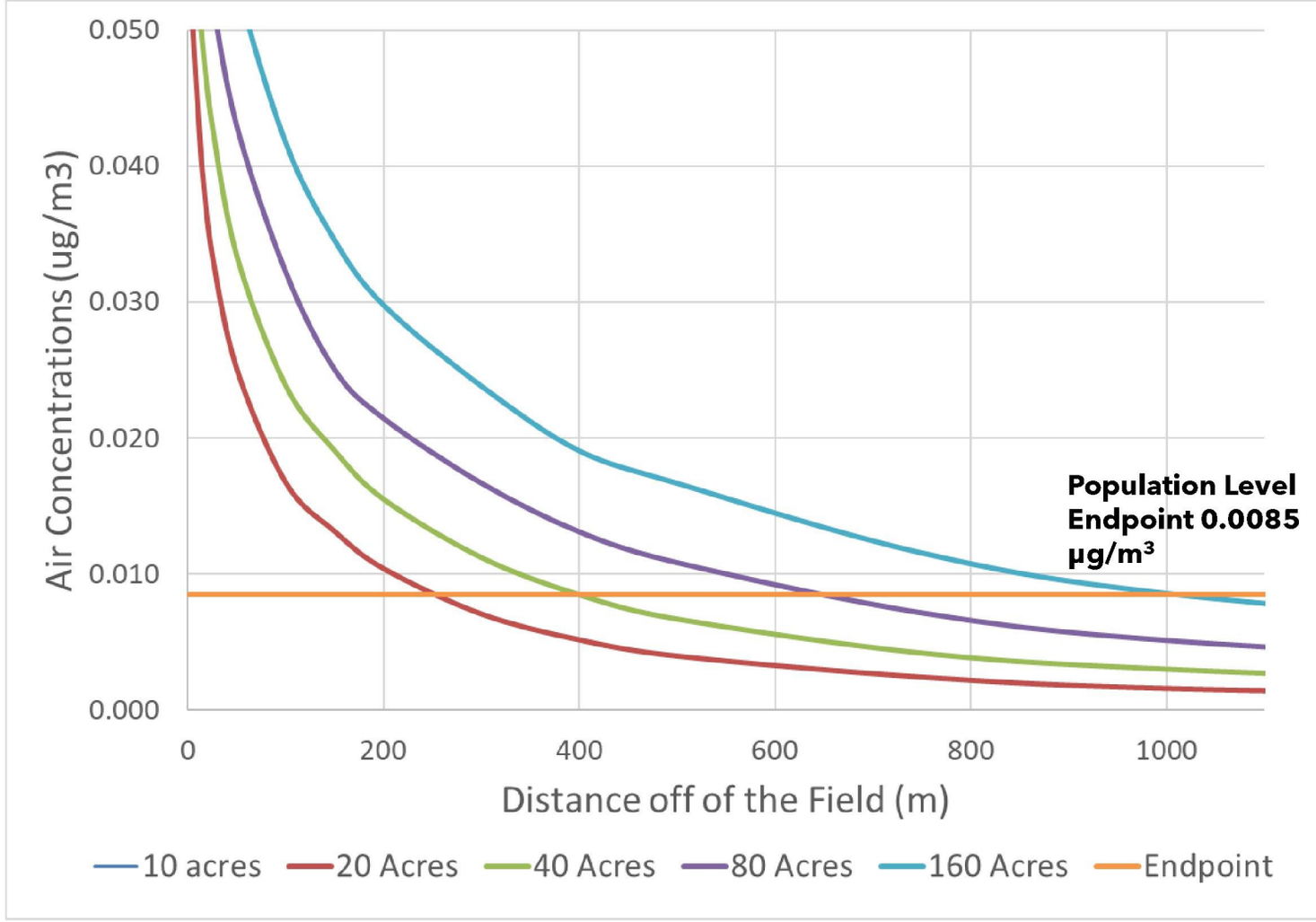
Typical Dicamba Flux Studies



*Red line marks 48 hours

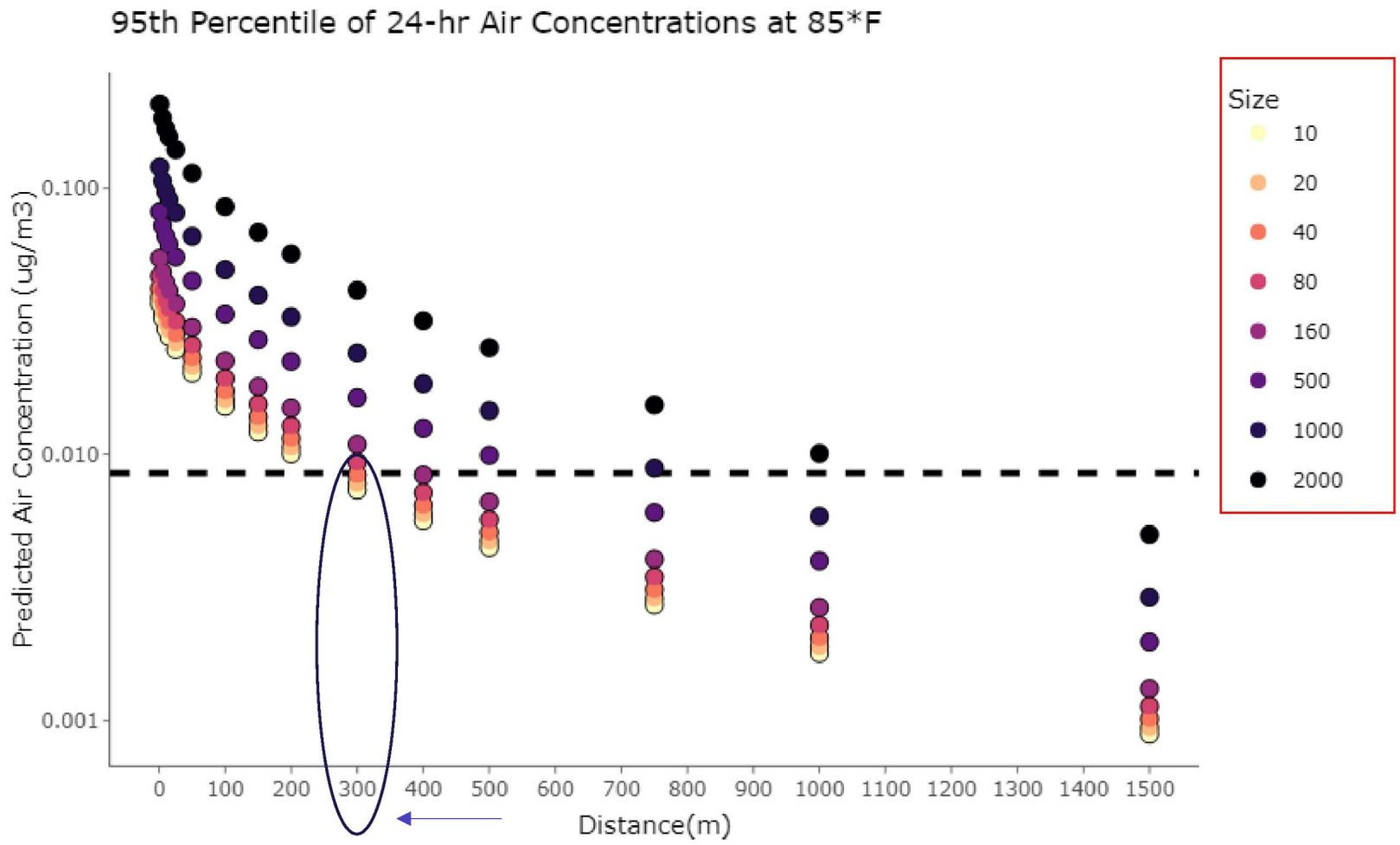
Near Field Volatility Exposure

- Figure is showing relationship with increasing air concentrations as area treated increases.
- Temperature is held constant.
- Exceedance of population level endpoint ranging from ~300 to 1000 m off the field.



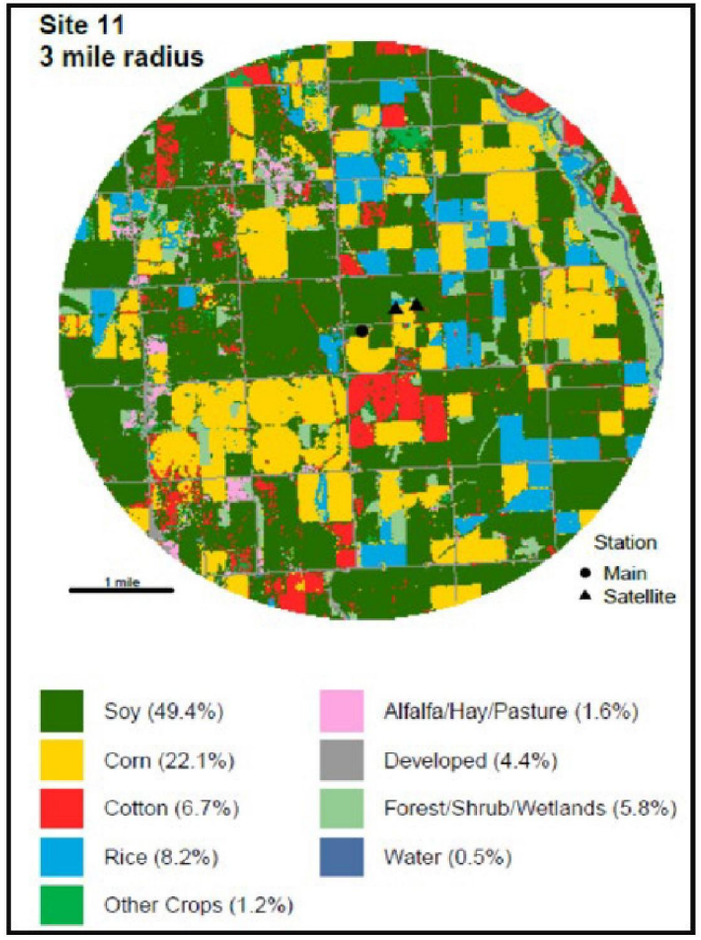
Area Wide Volatility Modeling

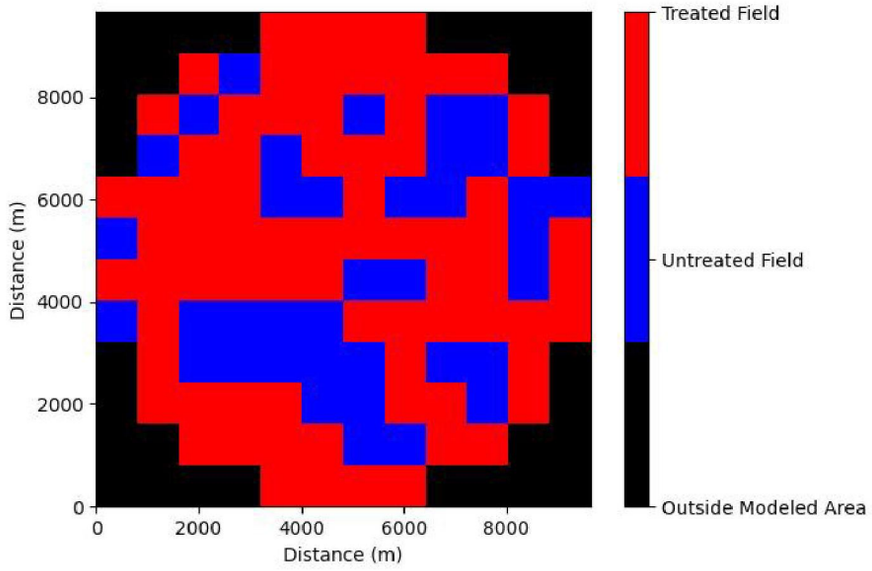
- Air concentrations increase as field size increases.
- Decreasing temperature from 93˚F to 85˚F, could decrease expected air concentrations by 40%.
- Finding distance where typical field size falls below endpoint



Area Wide Modeling with Varied Cropping and Application

- Tier 3 Modeling
  - landscape is varied
  - 3 locations with localized land use and weather
- Evaluated procedure, improved for risk assessment
- Gives an estimate for areas with percent cropped treated ranging from 30% - 50%.





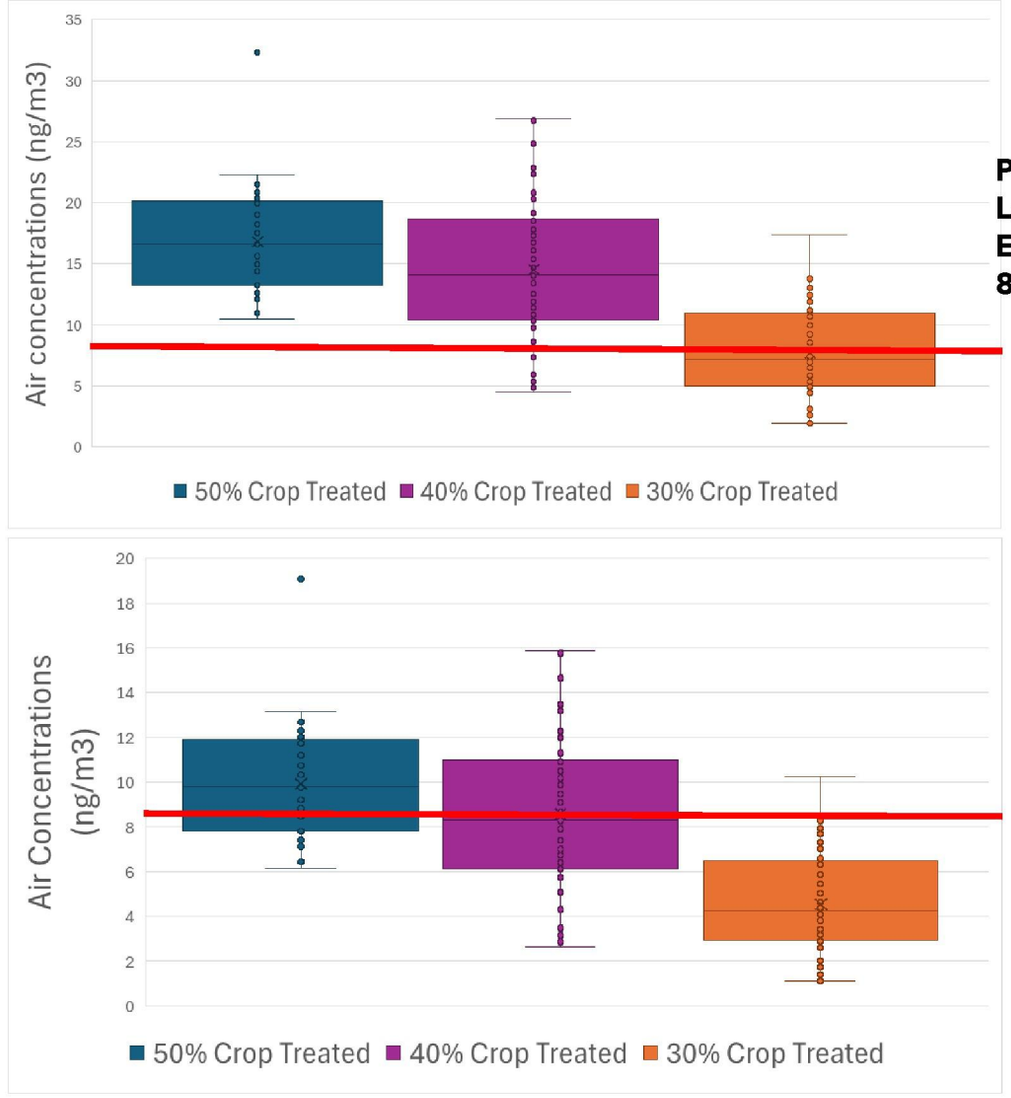
50% crop treated scenario

Area Wide Modeling with Varied Cropping and Application

- Air concentrations adjusted to 85 ˚F using relationship with temperature
- Central tendency drops below endpoint for most of the scenarios

95˚F

85˚F



Population Level Endpoint 8.5 ng/m³

Differences in Area Wide Analysis

Bayer

- Calculated exposure from center of landscape
- Averaged hourly air concentrations (misses peaks of exposure)
- 2 weeks for planting and 4 weeks for applications

EFED

- Looked at air concentrations across landscape
- Calculated 90th percentiles of max daily averaged air concentration (took same approach as PWC)
- 1 week for planting and 1 week for applications

WILL BE REMOVED IN SLIDE DECK FOR NON-BAYER REGISTRANTS

Summarize Volatility Conclusions

- pH: VRA is effective at reducing/suppressing volatilization
- Temperature: Strong connection between air concentration and temperature, thresholds are defensible at 75, 85 and 95 ˚F
- Landscape level applications:
  - lower likelihood of endpoint exceedance after accounting for typical patterns of % area treated at 85 ˚F
  - Reduced area treated (≥ 40%) mitigates the air concentrations occurring from applications between 85 and 95˚F

EPA Proposed Change to Volatility Mitigation (Option 1)

48 Hour Max Temperature	Need VRA?	Additional Mitigation
<75 ˚F	Yes (20 fl oz/A)	No
≥75 ˚F - <85 ˚F	Yes (40 fl oz/A)	No
≥85 ˚F	Yes (40 fl oz/A)	40% reduction in area treated [can treat 60% of field]* • Precision agriculture • In row drop nozzles • In row hooded sprayers • Partial field treatment • Spot treatment
≥95 ˚F	No applications	

*Treatment of the untreated 40% area can happen on day 3 (day 1 is app to the 60% of the field). Retreatment of a treated area cannot happen within 7 days.

EPA Proposed Change to Volatility Mitigation (Option 2)

Temperature	Mitigation
<75 ˚F	VRA (20 fl oz/A)
≥75 ˚F	VRA (40 fl oz/A)
≥85 ˚F	No Application

Discussion of Runoff/Erosion Mitigation Implementation

- **Option 1:** Use Strategies to set the mitigation and apply nationally (with respect to the state and county level restriction on label)
  - Update labels; need to generate a BE; formal consultation (7d); max mitigation would be on labels (no PULAs, 6 points nationally)
  - Faster than Option 2

- **Option 2:** Use Strategies to set the mitigation and apply within PULAs; Zero points nationally
  - Update labels; need to generate a BE; formal consultation (7d); mitigation would vary by PULA (work with applicant on PULA process)Would need to be EFED's top priority from now until October 2025, impacting other priority activities

Discussion of Runoff/Erosion Mitigation Implementation (cont.)

- **Option 3:** Use Strategies to set the mitigation and develop PULAs; apply 3 points nationally, 6 points within PULAs
  - Update labels; need to generate a BE; formal consultation (7d); mitigation would vary by PULA; would need to be a high priority for EFED, may impact other activities
  - There are 26 unique species in PULAs 5 & 6
    - 2 core maps are completed
    - 11 have core maps in progress
    - 13 have not been started

PULA Process

- Registrant creates PULAs and submits for review as they are available, rather than waiting to submit them all together.
- Unclear timeline of creation and review, because no registrant has submitted PULAs yet.
- Expect it will take a few (3-4) months to review, depending largely on how many PULAs there are (*e.g.*, 5 vs 40). There are multiple steps, from reviewing the data, to transforming the data, to bulletin creation.
- Bulletins based on PULAs must be established at time of registration
- Complicating factor for this action- some PULAs needed are already being worked on by others with no defined timeline
- This could only work if registrants get us PULA maps prior to publication of the proposed decision

Timeline Uncertainties

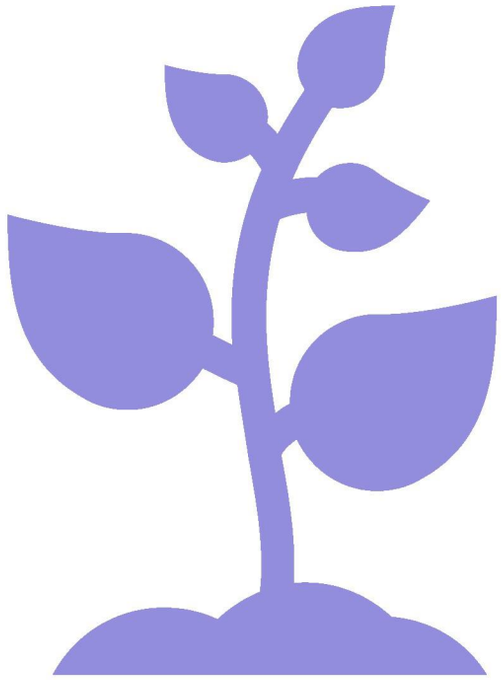
- Company collaboration
- Negotiation and discussion
- PULA Process
- Public Comments – NORs and Proposed decision
- Consultation timeline FWS and NMFS

Next Steps....

- Registrants' proposal resubmission- should be aligned.
- Complete effects determinations as needed
- Finalize mitigation commitments
- Complete EFED assessment
- Complete benefits assessment
- Complete label reviews
- Draft and publish proposed decision document, assessments, and labels with 30-day public comment period
- Publish final decision document, final labels, comments document addressing comments received on NORs plus comments received on proposed decision, and drafting 7(d) consistency finding, if necessary
- Initiate any necessary consultation with the appropriate Service(s)

Registrant response needed

- Which mitigation option to go forward with?
- How to manage spatial implementation of the runoff mitigations?
  - If PULAs are needed, what is the plan creation of those?
- Alignment plan for label restrictions and requirements?
- Maintain county restrictions?
- Ensure droplet size and boom height are clarified on labels.



Discussion