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# The Deal with Dicamba:

## Overview of Recent Legal Developments

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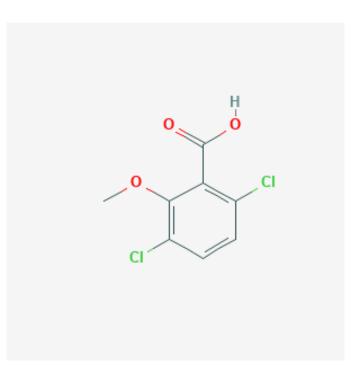
### Outline:





#### What is Dicamba?

- A chemical herbicide designed to kill broad-leafed plants
- Used on weeds that have developed glyphosate resistance
  - Ex: *palmer amaranth* aka pigweed
- Prone to volatility vaporizing into the air and traveling off target
- Historically applied as a preemergent in late winter and early spring to avoid volatility issues





### From Preemergent to OTT

In 2015, USDA approved new dicamba-resistant soybean and cotton seeds created by Monsanto Co. (now Bayer)

 At that time, dicamba was only approved for use as a preemergent



In 2016, EPA approved a label for a new, less-volatile dicamba-based pesticide called XtendiMax

- The label allowed XtendiMax to be applied directly to dicamba-resistant soybean and cotton seeds
- Engenia and FeXapan were approved in 2018



### Controversy soon followed

- Claims of damage from dicamba drift increased after 2015
- Ultimately, this led to lawsuits from environmental groups seeking to vacate overthe-top use of dicamba
- These lawsuits always claim that EPA violated FIFRA and the ESA



#### **FIFRA Basics**

- Before a pesticide may be legally used in the United States, it must have a label registered under FIFRA
- EPA is responsible for working registering pesticide labels and administering FIFRA
- To register a pesticide label, EPA must make a finding that the registered use of the pesticide will not have an "unreasonable adverse effect on the environment"
- FIFRA defines "unreasonable adverse effect" as:
  - "Any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."
- There are different types of labels available under FIFRA, but all must meet the "unreasonable adverse effect" standard



#### **ESA Basics**

The ESA was enacted in 1973 for the purpose of conserving threatened and endangered species and the ecosystems on which they depend

The ESA is administered by FWS and NMFS who are responsible for identifying and listing threatened and endangered species, and designating critical habitat

Listed species and designated critical habitat receive ESA protections

Federal agencies are required to consult with FWS and NMFS to ensure that the actions they carry out will not "jeopardize" listed species, or destroy critical habitat

#### First Lawsuit

The first lawsuit challenging over-the-top registration of dicamba was filed in 2016

 Claims made in this lawsuit would become standard for all following lawsuits

Plaintiffs argued that the XtendiMax label violated FIFRA and the ESA

- **FIFRA argument:** EPA failed to show that registering dicamba for over-the-top use would not cause "unreasonable adverse effects on the environment"
- **ESA argument:** EPA failed to go through mandatory consultation with FWS

Ultimately this first case was dismissed because the 2016 label expired before the lawsuit could reach trial

• Plaintiffs refiled to challenge the 2018 registration of XtendiMax, Engenia, and FeXapan

### Nat'l Family Farm Coal. v. EPA

- Lawsuit filed in 2018 in the Ninth Circuit Court of Appeals by environmental organizations
- Claims: EPA's 2018 registrations of the new formulation of dicamba violated FIFRA and the ESA
- **Requested relief:** Asked court to vacate the registration
- Ultimate outcome: The court issued an order to vacate over-the-top use of dicamba during the 2020 growing season





### 2020 Ninth Circuit Decision:

Additional analysis:



- The Ninth Circuit concluded that the 2018 pesticide registrations violated FIFRA because EPA wrongly concluded that the label amendments would not "significantly increase the risk of any unreasonable adverse effect on the environment" by:
  - Substantially understating the three risks that it identified, and
  - Failing to acknowledge three other risks
- Substantially understated risks:
  - (1) Amount of acreage planted with dicamba-resistant seeds in 2018
  - (2) Complaints of dicamba damage could have been either under-reported or over-reported
  - (3) No estimation of the amount of damage caused by application
- Unacknowledged risks:
  - (1) Substantial non-compliance with label requirements
  - (2) Economic costs
  - (3) Social costs

#### **Outcomes**

Over-the-top use of dicamba was vacated in the middle of the 2020 growing season

EPA issued a Cancellation Order that allowed use of existing stocks New over-the-top use labels were approved for XtendiMax, Engenia, and Tavium in late 2020 for the 2021-2025 growing seasons

 Added new restrictions, including federal cutoff dates and increased endangered species buffers New labels prompted new lawsuits



### Outline:





### The Headlines



- On February 6, a federal court in AZ issued a ruling to vacate over-the-top registration for three dicamba products
  - XtendiMax, Engenia, Tavium
  - All three were registered through the 2025 growing season
- EPA issued an order canceling OTT registration for the products, but will allow existing stocks to be used during the 2024 growing season
  - "Existing stocks" = products that were "labeled, packaged, and released for shipment" before Feb.
- This is the second time a court has vacated OTT use of dicamba

### Background



Ctr. for Biological Diversity v. U.S. Envtl. Protection Agency was initially filed in late 2020 to challenge EPA's approval of over-the-top use of dicamba for the 2021-2025 growing seasons



The case was initially paused after the Biden administration took office and was on hold for over a year



Plaintiffs once again argued that the 2020 dicamba registration violated both FIFRA and the ESA



### FIFRA Claims

Plaintiffs raised three main FIFRA arguments:

The 2020 registration failed to address the FIFRA violations identified by the Ninth Circuit in its June 2020 decision

When EPA registered dicamba for over-the-top use in 2018, it issued a conditional registration which allowed EPA to seek further data – the 2020 registration was an unconditional registration which can only be made when no additional data is needed; EPA failed to explain why the change was made despite relying on the same data as the 2018 registration

EPA failed to show that the 2020 registration would not cause "unreasonable adverse impacts on the environment"



#### **ESA Claims**

Plaintiffs also raised three ESA claims:

EPA failed to conduct ESA consultation – the agency applied the wrong standard to determine that consultation was not needed

EPA considered an incorrect "action area" when considering species impacts

EPA wrongly concluded that the 2020 registration decision would not harm critical habitat

#### **Procedural Claims**

- Separate from the substantive FIFRA and ESA claims, plaintiffs also raised two procedural claims
- First, plaintiffs argued that the 2020 registration decision violated the FIFRA process for "un-cancelling" a previously cancelled pesticide
  - When a pesticide is formally cancelled, FIFRA requires EPA to find "substantial new evidence" indicating that re-registration is warranted
  - Plaintiffs argue that EPA did not do this
- Second, plaintiffs claim that the 2020 registration decision did not follow notice-and-comment rulemaking requirements
  - FIFRA requires a 30-day public comment period if a pesticide registration would "entail a changed use pattern"
  - Plaintiffs argue that EPA should have provided this "new use" comment period because at the time EPA re-registered over-the-top use of dicamba it was a new use



# The Court's Decision:

Additional Analysis:



- The AZ district court found that EPA had violated FIFRA procedural requirements when registering OTT use in 2020
- FIFRA "new use" registrations mandate a period of public notice-and-comment
- EPA argued that the 2020 OTT registrations were not "new use," but the court disagreed
  - EPA argued that because Tavium was not affected by the 2020 ruling, it could pursue a "me-too" registration for XtendiMax and Engenia
  - But because Tavium itself had been registered under FIFRA's "me-too" provision, the court was not convinced
- The court also noted that when reapproving a cancelled registration, notice-and-comment is also required

### Aftermath

The court's decision vacated the labels for XtendiMax, Engenia, and Tavium

• Following the decision, there were no dicamba products still registered for over-the-top use

The decision was issued on February 6, 2024, after many farmers had purchased seed

EPA issued an Existing Stocks Order on February 14 to allow some use during the 2024 season

• After 2024, things are more uncertain

Defendants had 60 days to file an appeal – neither EPA or Bayer filed within that time period

Without an appeal, the decision will stand



## **Existing Stocks Order**

EPA issued an Existing Stocks Order on Feb. 14

Prohibits use of these products except as consistent with the labeling

The dicamba products are no longer registered under FIFRA, but existing stocks can be used during the 2024 growing season

- "Existing stocks" is defined as "those stocks of previously registered pesticide products that are currently in the United States and were packaged, labeled, and release for shipment prior to Feb. 6, 2024"
- A product has been "released for shipment" when the producer has "packaged and labeled it in the manner in which it will be distributed or sold, or has stored it in an area where finished products are ordinarily held for shipment"

EPA establishes cut-off dates for sale and use of existing stocks

• Dates vary by state, but no applications to soybeans can be made after June 30 or to cotton after July 30

#### Outline:





#### What's Next?



- The future of over-the-top dicamba use post 2024 is murky
- Manufacturers are looking to reregister over-the-top use of their products, but the path forward is likely to be difficult
- Any future registration will likely face legal claims that it violates FIFRA and the ESA



## Possible Challenges

#### **FIFRA Considerations**

- Resolve procedural issues?
  - Follow FIFRA process to "uncancel" a pesticide? Seek full unconditional registration?
- Resolve issues highlighted by the Ninth Circuit?
  - The AZ court did not reach this argument so unclear how future courts would treat it
- Reduce confusion with label instructions?
  - Courts have found previous labels to be too long and difficult to follow – how can EPA resolve this?

#### **ESA Considerations**

- Will EPA go through ESA consultation?
  - Likely to be time-intensive could add months to years to the process
- How will new ESA-FIFRA policy come into play?
  - Likely to add additional use restrictions
  - Could alleviate need to go through ESA consultation – too soon to say



# Bayer Resubmits:

Label information and comment submission available here:



- In March, Bayer submitted a new XtendiMax label to EPA for use on dicamba-resistant soybean and cotton seeds in 2025
- This label is more limited than previous labels and would only allow the following:
  - Up to two applications to soybeans either prior to emergence or up to June 12 – no over-the-top application for soybeans would be allowed
  - Post-emergent use for cotton through July 30
- The label is currently available for public comment

#### Timeline?

New XtendiMax label is for the 2025 growing season, but the overall timeline remains uncertain

Current public comment period is for 30 days, but that may be extended

• Various groups have indicated they will push for at least 60 days of comment

The label was submitted as an R170 additional food use label which carries a mandatory review period of 17 months from the time the action begins

This would have review concluding in fall 2025

ESA consultation would likely add additional time

- Action area covers over 30 states where hundreds of threatened and endangered species are located
- EPA has other court-mandated ESA deadlines it is also working to meet



### Additional Hurdle: New ESA-FIFRA Policy

- Broadly, EPA's new ESA-FIFRA Policy focuses on "early mitigations"
  - These are new restrictions that will be added to pesticide labels to reduce impacts to listed species and critical habitat
- The goal of introducing early mitigations is to reduce the number of future ESA consultations that result in findings of "jeopardy" or "adverse modification"
- EPA is developing these early mitigations in two ways:
  - Broadly across different groupings of pesticides (herbicides, insecticides, rodenticides, etc.)
  - Tailored to address species that are considered particularly vulnerable to pesticides
- Both the Herbicide Strategy and Vulnerable Species Program could result in additional restrictions being added to future over-the-top dicamba labels



# Draft Herbicide Strategy

Outlines early mitigations that EPA expects to include on all herbicide labels

Early mitigations fall into two main categories – reducing pesticide spray drift, and reducing pesticide runoff/erosion

Mitigation measures EPA finds are necessary across the entire pesticide use area will be included in the product's general label

Mitigation measures only necessary in specific geographic areas will be posted to EPA's website Bulletins Live! Two



# Draft Herbicide Strategy: Mitigations

#### **Spray Drift Mitigations**

 Additional buffer requirements in the form of windbreaks, hedgerows, hooded sprayers, and application rate reduction depending on level of risk

#### **Runoff/Erosion Mitigations**

- A "mitigation menu" of limitations applicators choose which methods are right for them to achieve the necessary number of "points"
- Includes: weather-based restrictions; methods of application; in-field management activities to reduce runoff; management adjacent to sprayed fields; activities to increase water retention



### Vulnerable Species Pilot Program

Introduces early mitigation measures targeted at "vulnerable species" which EPA has identified as being at the greatest risk of pesticide exposure

These mitigations would apply broadly to conventional pesticide active ingredients and fall into two broad categories – avoidance and minimization

Avoidance mitigation refers to areas where pesticide applications would be prohibited

Minimization mitigations focus on reducing spray drift, and runoff/erosion

Because VSPP mitigations are geographically specific, they will be posted to Bulletins Live! Two



### **VSPP:** Mitigations

#### **Spray Drift Mitigations**

- Spray drift buffers
- Prohibition of application methods or droplet sizes

#### **Runoff/Erosion Mitigations**

- No applications when soil is saturated
- No applications when rain is in the forecast
- Requirement of land use practices designed to reduce runoff or erosion



## Implications for Dicamba

### A final herbicide strategy is expected August 30

- Restrictions likely to start appearing on herbicide labels late this year or early next
- Any new dicamba label likely to be impacted
- Reminder: previous over-the-top dicamba labels already had strict buffer zones and spray drift restrictions

# EPA plans to add additional species to the VSP

• More species = more restrictions



### Other Labels?

- BASF may resubmit a label for Engenia
  - Has not happened yet, but is likely
- Syngenta may also resubmit for Tavium
  - Also has not happened yet
- Unclear whether either label would look different from resubmitted XtendiMax label
  - Over-the-top for soybeans still up in the air





#### Outline:





### Final Thoughts

- Existing Stocks order provides guidance for 2024, but 2025 and on is still uncertain
  - Bayer label likely not to be approved by next growing season
  - Future of over-the-top use on soybeans unclear
- AZ court ruled on procedural grounds – this has pros and cons
  - Procedural violations are more easily fixed
  - Substantive issues remain unresolved
- ESA issues still lurking
  - Any label approved without ESA consultation remains vulnerable





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