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Agriculture Division of DowDuPont™

# Transform® WG and the US Regulatory Process

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# Outline

- Transform WG registration history
  - Original registration
  - Current label
  - Pollinator risk assessment and proposed label additions
- Efficacy of Transform
- US Regulatory Process
  - Various types of registrations – process, pros and cons
  - Section 3
  - Section 24(c)/SLN
  - Section 18

# Original Transform Registration

- Active Ingredient: sulfoxaflor (now branded as Isoclast®)
- Unconditionally registered by US EPA in May 2013
- In opening docket for public comment in January, 2013 EPA proposed conditional registration
  - Conditional upon data regarding bee brood effects and long term colony health
  - Label originally proposed had higher application rates and more flexibility regarding application timings during bloom
- "After review of the public comments and further consideration of the database, EPA has concluded that an unconditional registration of sulfoxaflor, with lowered application rates and other mitigation…is supported by the available data and therefore the appropriate regulatory decision." (EPA registration decision document, May 2013)

# Original Transform Registration

- Pollinator data package included:
  - Acute toxicity to adult and larval honeybees
  - Chronic toxicity to larval honeybees
  - Aged residue testing – not persistently toxic
  - 6 semi-field “tunnel” studies
  - Nectar/pollen residue data from cotton, pumpkin, *Phacelia*
  - Bumblebee acute toxicity data
  - Acute toxicity of metabolites
- *Data requirement have/continue to evolve*

# Pollinator Studies

Two colonies enclosed, one at each end of tunnel
Tunnels covered with bee-proof netting (180 x 25 x 10ft)
Colony condition checked
- 3 days before exposure
- 10 days after exposure (after tunnel confinement)
- 17 days after exposure (at remote location for 1 week)

Each colony (10 frames) was healthy with active queen when placed in tunnel

# Original Transform Registration

- In July 2013, Pollinator Stewardship Council, American Honey Producers Association, National Honeybee Advisory Board, American Beekeeping Federation and 3 Beekeepers filed suit against EPA in US 9th Circuit Court of Appeals
- Suit alleged that EPA had lacked valid “Tier II” data for decision, relied on inadequate mitigation, and improperly weighed risks vs. benefits
- *Chief issue – EPA’s explanation of registration decision*

# Original Transform Registration

- November 2015: 9th Circuit Court opinion disagreed with USEPA's conclusions regarding the science and the regulatory process
  - "Because the EPA's decision to unconditionally register sulfoxaflor was based on flawed and limited data…We therefore vacate the EPA's registration of sulfoxaflor and remand."
- *Litigation – or threat of litigation – is the biggest issue in development and registration of crop protection products*

# Current Transform Registration

- In October 2016, new Section 3 label was approved
- Structured to prevent pollinator exposure
  - Indeterminate blooming crops not on label
  - Restrictions on application timing for most other crops
  - 12 foot, downwind buffer to blooming vegetation

# New Data for Risk Assessment

- New studies submitted to EPA:
- Adult & chronic larval toxicity
- Two tunnel studies (Tier II)
- Two colony feeding studies (Tier II)
- Nectar and pollen residues on a number of crops (Tier II)

# Future Label

- EPA currently evaluating data
- Label proposed by Corteva to include all original crops:
  - Cotton, soybean, citrus, cucurbits, strawberry
- New crops proposed include alfalfa, sorghum, corn
  - Tolerance petitions pending for several years
- Expect a public comment period in early 2019

# Colony Feeding Study

Colonies placed in buckwheat field

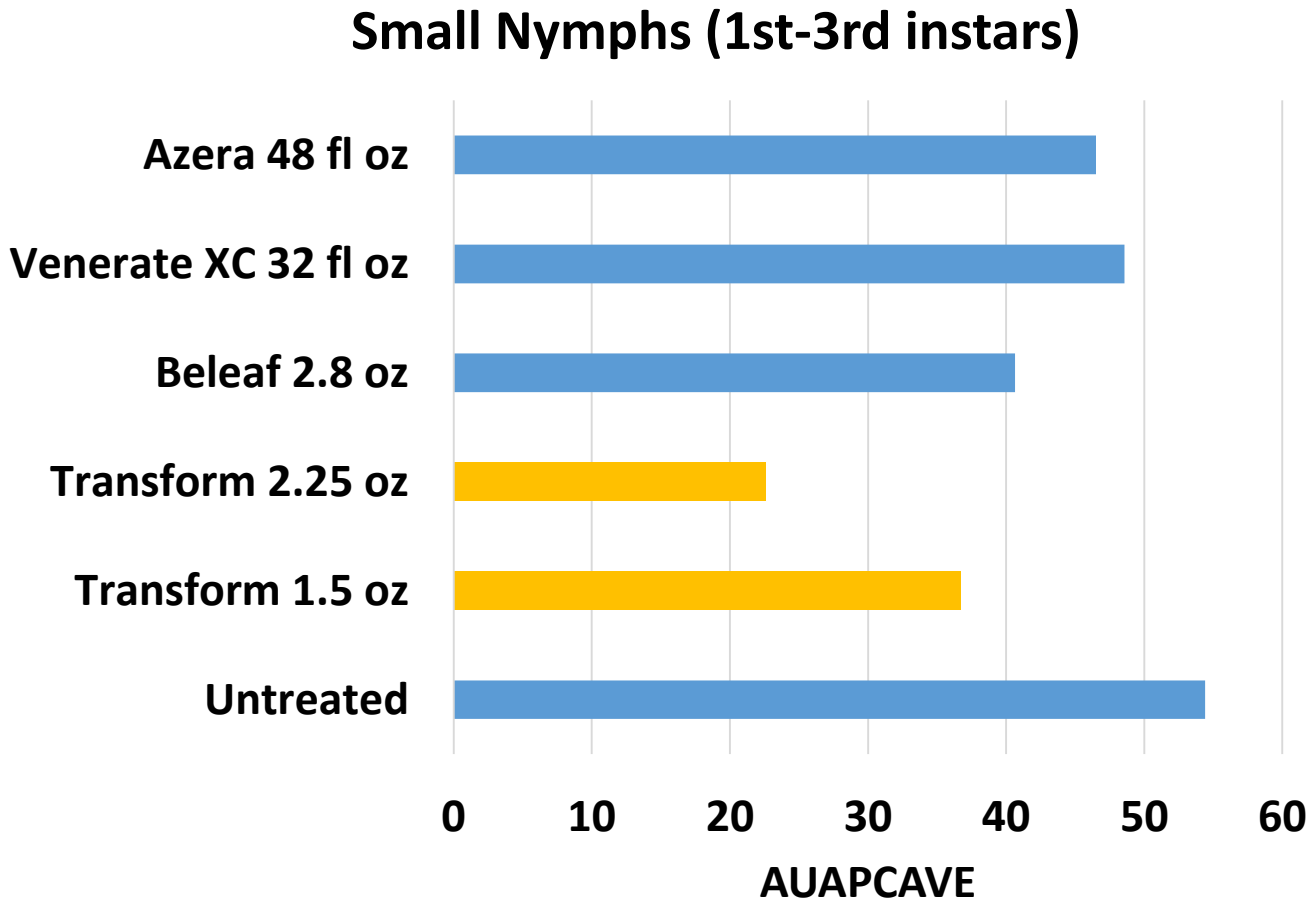
What's left after a bear eats your colony

# Tunnel Study

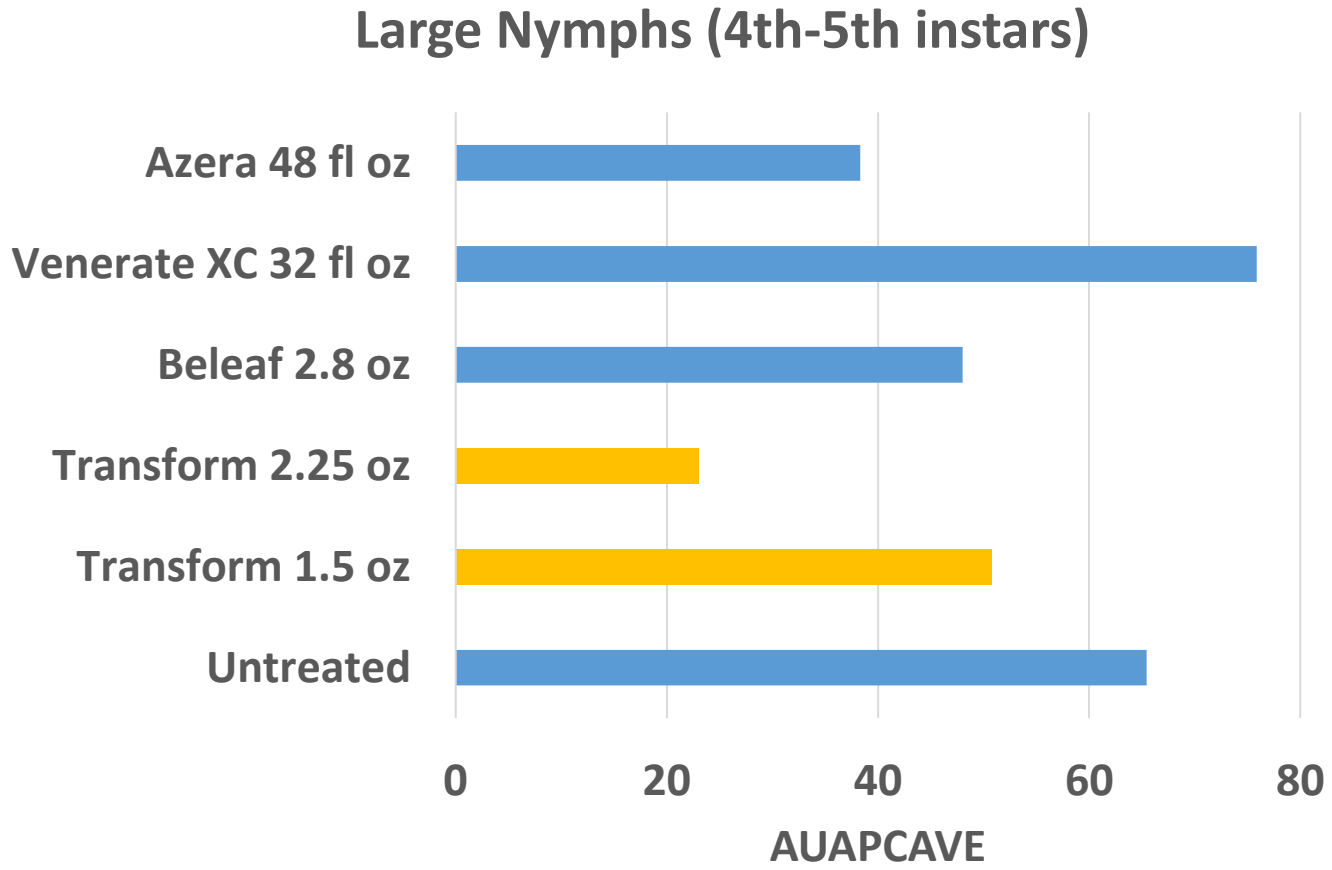
# Transform Efficacy in Alfalfa

# Lygus in Alfalfa Seed

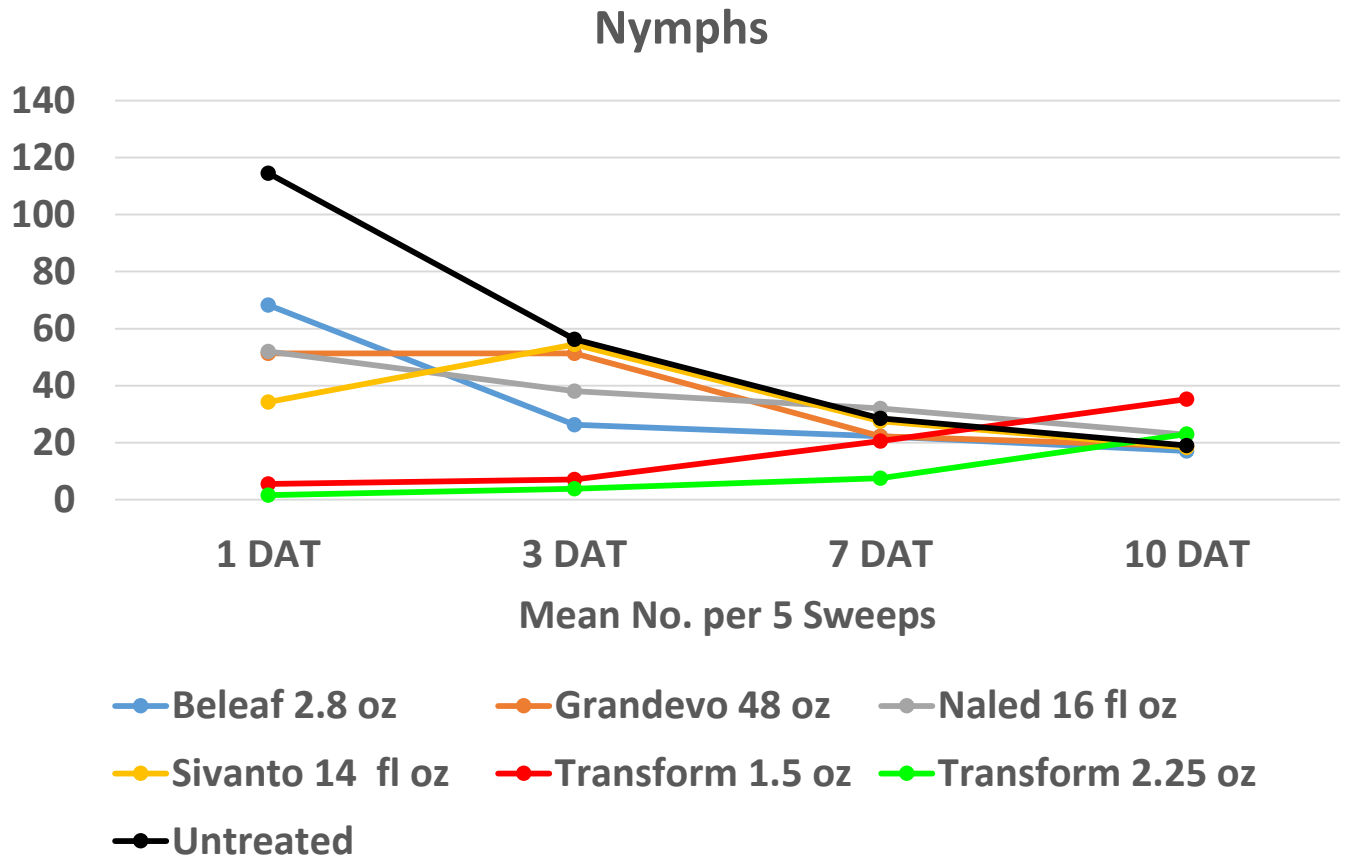
## J. Barbour, Univ. of ID, Parma - 2017



# Lygus in Alfalfa Seed
## J. Barbour, Univ. of ID, Parma - 2017

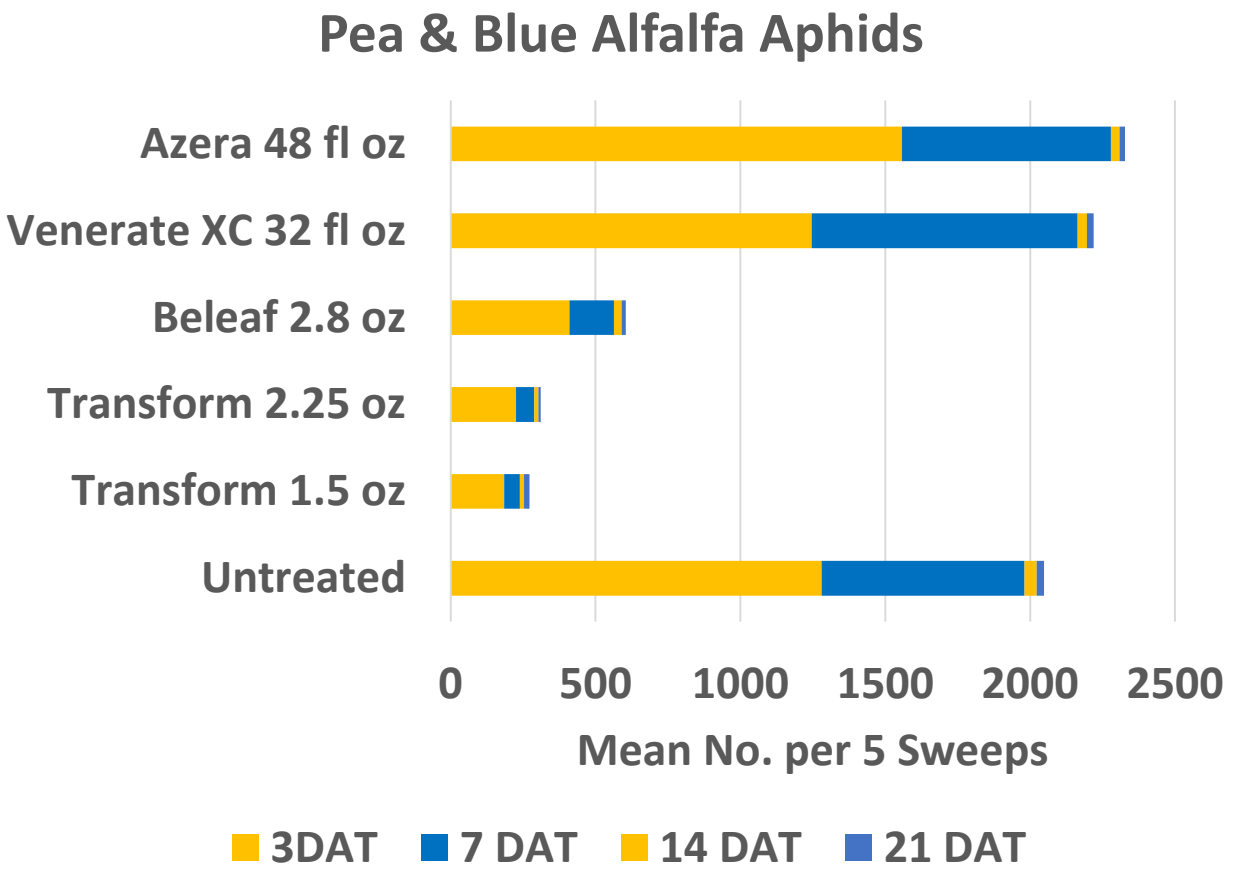


# *Lygus* in Alfalfa Seed
## D. Walsh, WSU, Prosser - 2017



# Pea & Blue Alfalfa Aphids in Alfalfa Seed

## J. Barbour, Univ. of ID, Parma - 2017



# The Regulatory Process

# Pesticide Registration

- A **method of regulating** pesticides to ensure that their use does not cause unreasonable adverse effects on human health and the environment
- A **legal requirement**, enforced by the U.S. Environmental Protection Agency (EPA) and the States.
- A "**license**" required in order to distribute or sell a pesticide

# Pesticide Registration

- **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)** - Requires all pesticides sold or distributed in the U.S. to be registered by EPA and the States.
- **Federal Food, Drug and Cosmetic Act (FFDCA)** - Regulates the establishment of pesticide tolerances (MRL). A tolerance is the maximum permissible level of a pesticide residue allowed in or on commodities used for human food and animal feed
- **Food Quality Protection Act (FQPA) of 1996-** Amended both FIFRA and FFDCA, EPA must follow additional criteria for the registration of pesticides, including new considerations of exposure for infants and children.
- **Pesticide Registration Improvement Act-** The consolidated Appropriations Act of 2004 established a new Section 33 of FIFRA requiring a registration service fee system as of March 23, 2004

# Pesticide Registration

- Federal Registrations:
  - **Section 3 - Full Registration**
  - Section 5 - Experimental Use Permit
- State Registrations & Submissions:
  - **Section 3 - Full Registration**
  - **Section 24(c) - Special Local Needs**
  - **Section 18 - Emergency Exemption**
  - Section 5 Fedl. EUP or State EUPs
  - Sec 2(ee) – Product Use Bulletins

# Section 18 vs. 24(c)

| Section 18 | 24(c) |
|---|---|
| An exemption from one or more aspects of FIFRA due to emergency | Special Local Need (SLN) label specific to state |
| Used for unregistered product, or crop on which product not registered | Tolerance exists, crop is on label (can be some exceptions) but used for new application type or restriction, for example |
| Requested by 3rd party; Registrant cannot request a Section 18 | Requested by Registrant or 3rd party |
| State regulatory agency submits application to EPA; EPA must approve | State approves label and submits to EPA; EPA not required to approve, ***but can deny*** |
| State is "registrant" | Requestor is registrant |
| Usually in effect for 1 year or less | Can be open ended but usually limited to several years |

# Section 18 vs. 24(c)

- Both require 3rd party support; typically university or grower group(s)
- Initial Section 18s require more documentation of need and economics
  - Section 18s more difficult to obtain, but may be fast-tracked in subsequent years
  - States becoming more challenging on 24c
- State regulatory agencies usually depend heavily on 3rd parties to construct Section 18 applications
  - Most often university, but grower groups can contribute and sometimes lead effort
- Registrant carries load for 24c, 3rd parties usually only have to provide letter of support

# Questions?