

# 2026 ASI Annual Convention

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# US Regulatory Pathways

- **EPA Regulated**

- **Section 3 registration**

- This is the standard pathway for pesticide products in the US
- It can take decades to develop the data and move through review depending on the pesticide's properties and proposed use

- **Section 18 authorization**

- This type of authorization is used for emergency purposes such as entry of a new pest into the US creating a significant threat to agricultural crops or, animals where appropriate management products have not been established (example NWS)
- Supportive data are required for efficacy, safety, and withhold requirements

- **2(ee)**

- This is an option available to the states which allows addition of only a new pest vs. use, site, application, dose, etc.

- **FDA Regulated**

- **NADA**

- This is the standard pathway for drug products in the US
- It can take decades to develop the data and move through review depending on the drug's properties and proposed use
- ELDU applies

- **Conditional Approval – FDA**

- This pathway allows “conditional” approval of a product while efficacy data are still being generated, allowing earlier entry of the product into the market.
- ELDU is not permitted

- **Emergency Use Authorization (EUA)**

- EUAs are used in cases of emergency and are similar to Section 18 registrations
- Supportive data are required for efficacy, safety, and withhold requirements
- ELDU is not permitted

\*Veterinary extra-label drug use (ELDU) is a legally permitted practice where veterinarians use FDA-approved drugs in ways not listed on the label (different species, dose, indication, etc.), under strict conditions set by the Animal Medicinal Drug Use Clarification Act (AMDUCA)

# How?...do we respond?

- NWS Case Map
  - [NWS Case Map \( https://www.gob.mx/senasica/acciones-y-programas/gusano-barrendador-del-ganado \)](https://www.gob.mx/senasica/acciones-y-programas/gusano-barrendador-del-ganado)
- USDA HUB FOR NWS RESPONSE
  - [Screwworm.gov](https://www.screwworm.gov)
- USDA NWS response playbook
  - <https://www.aphis.usda.gov/news/agency-announcements/usda-shares-new-world-screwworm-response-playbook>
  - [USDA NWS Factsheet:](#)
- FDA NWS Protocol
  - <https://www.fda.gov/animal-veterinary/safety-health/new-world-screwworm-information-veterinarians>
  - [FDA NWS EUA for Dogs Press Release](#)
- Screwworm Coalition of Texas
  - [Texas Screwworm Resource Website \( https://screwwormtx.org \)](https://screwwormtx.org)