

# Atoxigenic *A. flavus* the path forward

<http://www.epa.gov/fedrgstr/EPA-PEST/2007/October/Day-26/p20828.htm>



A photograph of a misty landscape. In the foreground, there is a grassy field with some taller green plants. Several palm trees of varying heights are scattered across the middle ground. The background is a hazy, overcast sky, suggesting a foggy or rainy day. The overall tone is muted and atmospheric.

Exposure

Inhalation, Eye, Dermal

Rats, Birds, Fish, Bees,  
Plants



## Registration development phases- African Atoxigenic *A. flavus*

- Phase 1 Lab and Field testing for strain selection
- Phase 2 Conditional registration- “Experimental Use Permit”
- Phase 3 Field development- Application technology, GMP, Toxicology studies
- Phase 4 Registration
- Phase 5 Refinement of strain selection
- Phase 6 Registration of additional strains



## African Atoxigenic *A. flavus*

- Product Chemistry- Develop all applicable data. Mixture of inoculated grains - No waivers.
- Residue analysis- No true residue studies, but develop information on the impact of African **Atoxigenic *A. flavus*** on aflatoxin and total *A. flavus* community structure.
- Establish an exemption from tolerance for the strains.



## African Atoxigenic *A. flavus* –What do we know?

- **AF36 is a strain of the same organism and has been reviewed and registered in the US.**
- **Atoxigenic strains have been isolated in 20 African countries.**
- **Around 25,000 *A. flavus* isolates have been collected from Africa and 3,000-5,000 isolates are atoxigenic.**
- **In Kenya about 3,500 isolates have been collected with 600-700 atoxigenic isolates.**



## African Atoxigenic *A. flavus* –What do we know?

- **Research in Nigeria on 7 Ha over 5 years has involved:**
- **Handling of the organism in inoculum production, weighing, application, harvesting, shelling and milling by 9 permanent staff and 35 casual staff without any adverse effects.**



## African Atoxigenic *A. flavus* –Human Health

- **Acute oral rat- AF36 LD50 > 5000 mg/kg**  
**Conduct toxicology study on mixed/individual? strains for conditional registration with African atoxigenic *A. flavus*. and additional strains (if strains are changed) for final registration.**
- **Acute Pulmonary – EPA determined that AF36 is non toxic and non infective. Waive for conditional registration and final registration.**



## IITA Atoxigenic *A. flavus* –Human Health

- **Acute Inhalation-Waived for AF36. Should be waived for IITA Atoxigenic *A. flavus* during a conditional registration and also waived for permanent registration if there are no adverse effects from Pulmonary study.**
- **Acute dermal- Waived for AF36**



## African Atoxigenic *A. flavus* –Human Health

- **Acute Dermal, Injection, Eye irritation, Primary Dermal and sensitization- Waived for AF36, should be waived for conditional and permanent registration of African atoxigenic *A. flavus* assuming there are no adverse effects during acute oral study.**



## African Atoxigenic *A. flavus* – Non-target organisms

- **Avian oral- Waived for AF36. Should also be waived for African strains if no adverse affect in acute oral rat study.**
- **Avian Inhalation- AF36 no toxic affect at  $1.44 \times 10^5$  cfu/bird (5 days) after 30 days on bobwhite quail. Request waiver for African strains**



## African Atoxigenic *A. flavus* – Non-target organisms

- **Wild mammal testing- Waived for AF36.  
Wave for African strains if no adverse affects  
in acute oral rat study.**
- **Honeybee- Studied for 30 days on AF36  
indicated no adverse affect.  
Should conduct observational study with  
African strains by treating foraging plants in  
bloom.**



## African Atoxigenic *A. flavus* – Non-target organisms

- **Freshwater fish, Freshwater invertebrates, marine animals, non-target plants and other non-target insects.- Waived for AF36, propose waiving for African strains.**
- **Waive all higher tier studies.**



- **Efficacy Studies?**

