

## REGULATORY SUMMARY OF AF-36

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Strains of *Aspergillus flavus* produce aflatoxin, a potent microbial compound associated with animal toxicosis and other adverse effects. Aflatoxin contamination of cottonseed causes significant losses for the animal feed industry annually. Few alternatives, if any, exist to control aflatoxin-producing *A. flavus* strains in cotton and other crops. USDA Agricultural Research Service researchers have devised a method to displace toxigenic strains in the agro-ecosystem with more benign strains of the fungus. The AF36 strain of *A. flavus* is one of these benign strains and requires regulatory consideration as a microbial pesticide. The data requirements to support the safety finding for an experimental use permit (EUP) and registration of a microbial pesticide are found at 40 CFR 158.740. There are also guidelines suggesting how the studies should be done (OPPTS Harmonized Guidelines 885 series). The typical course of a registration action includes the review of safety test data supporting an EUP while more specific data, if needed, to justify the commercial registration is developed. The process for AF36 was somewhat different than the typical course for a microbial pesticide registration. Rather than submitting the toxicity/pathogenicity data for a safety determination, a large EUP with extensive monitoring was chosen to address possible increased exposure to this ubiquitous fungus. Given reports in the published literature regarding infectivity of *A. flavus*, there were still concerns about pathogenicity and efficacy to be addressed for the registration decision. The EUP phase was used to generate the fungal ecology information related to AF36 and its levels over the growing season compared to the indigenous *A. flavus* strains. Toxicity/ pathogenicity studies in rodents and other test species were done to address issues related to reports in the literature regarding reports of pathogenicity for this species. The registrant was also required to generate efficacy data since control of microbes producing mycotoxins is considered a claim to control microbes that pose a public health threat. The data submitted and reviewed will be discussed in the context of typical microbial pesticide registration and the flexibility of that process.