

# Mycotoxin Test Kit Program



## **GRAIN INSPECTION ADVISORY COMMITTEE**

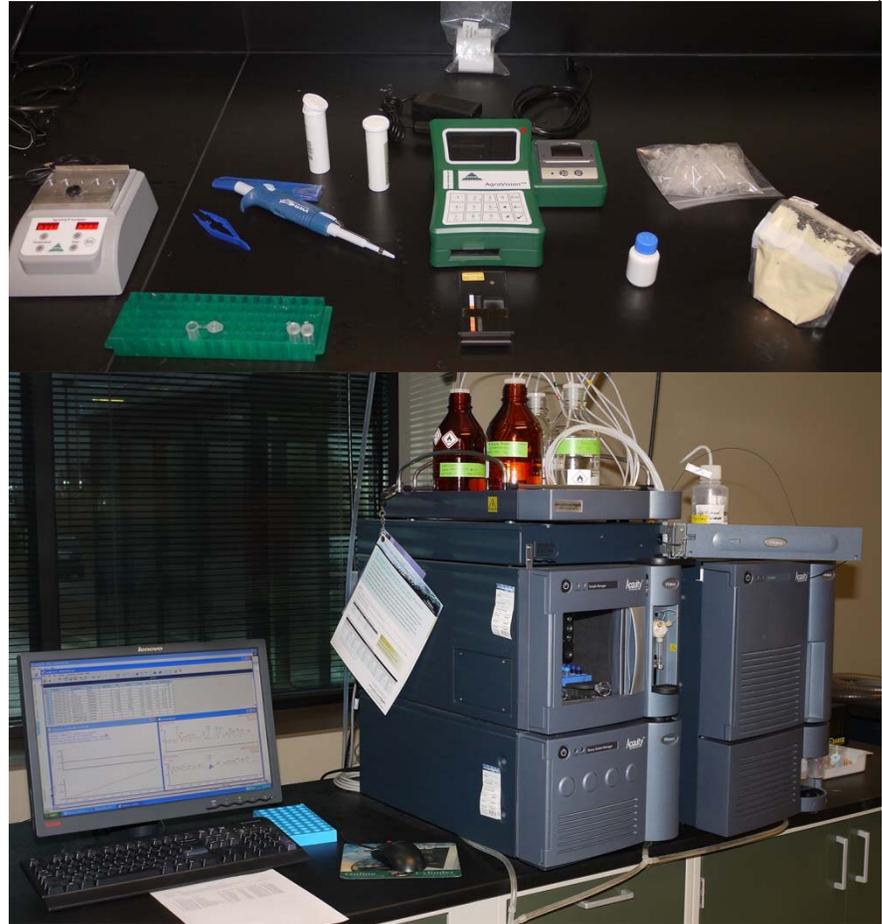
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**Office of the Director**  
**Technology and Science Division**  
**November 4 – 5, 2014**



**United States Department of Agriculture**  
Grain Inspection Advisory Committee Meeting, November 2014

# Official GIPSA Mycotoxin Testing

- **Rapid Test Kits**
  - GIPSA-approved kits only
  - Immunoassay methods
  - Inspections nationwide
- **Reference Methods**
  - Accuracy benchmark for GIPSA mycotoxin test kit evaluation program
  - Board appeal inspections
  - TSD only



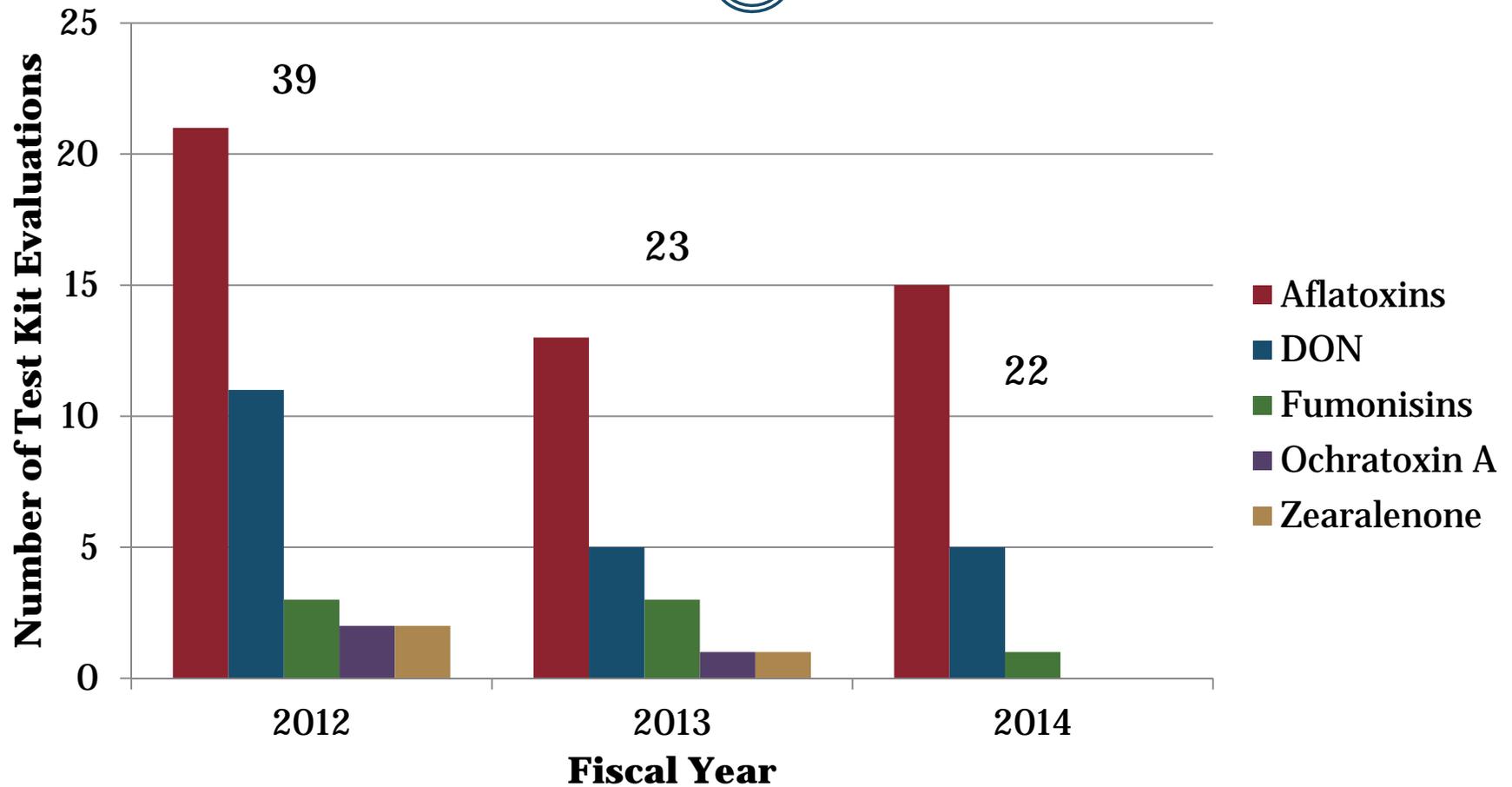
# Rapid Test Kit Evaluation



- Rapid quantitative & qualitative test kits
- GIPSA establishes performance requirements
- Test kit manufacturers submit data for review
- GIPSA verifies performance
- Pass – approved and certificate issued
- Fail – manufacturer redesigns and resubmits



# Mycotoxin Test Kit Evaluations



# Resolution 10



The Advisory Committee supports continued focus on water-based quantitative mycotoxin test kits. Industry efforts to be "green" by reducing use of hazardous chemicals and associated waste are becoming commonplace. Encouraging manufacturers of testing methodology to develop the water-based methods should be continued.



# Resolution 12



**The Advisory Committee recommends continued work in verifying the accuracy of mycotoxin test kits for Distillers Dried Grains with Solubles (DDGS).**



# GIPSA-Approved Quantitative Test Kits



Mycotoxin	Number of Test Kits			
	Water-Based Extraction		Organic Solvent Extraction	
	Total	DDGS	Total	DDGS
Aflatoxin	4	1	10	7
DON	10	3	0	0
Fumonisin	1	0	3	0
Ochratoxin A	0	0	2	0
Zearalenone	0	0	3	3

DDGS = Distillers Dried Grains with Solubles



# Supplemental Analysis



- **Definition**

Supplemental analysis is a procedure followed when a result is observed above the upper limit of the concentration range in GIPSA's test kit performance criteria and it is performed at the request of the applicant.

- **Example – 175 ppb aflatoxins**

Supplemental analysis is performed by diluting extract into the 5 – 100 ppb range and retesting. Result from diluted sample is multiplied by a dilution factor to yield final result.



# Supplemental Analysis



- **Problem #1 – Accuracy not evaluated under current GIPSA performance criteria**
- **Problem #2 – Increased complexity leads to errors**
  - Each test kit has a different procedure
  - Added steps, time, and possibilities for error
  - Increase in errors attributed to supplemental analysis in recent aflatoxin check sample distribution



## Resolution 5



Whereas GIPSA is exploring the possibility of expanding the concentration ranges in performance criteria for mycotoxin test kits, the Advisory Committee recommends GIPSA consider setting the following ranges for performance criteria:

**Aflatoxin - 5 to 700 ppb**

**Vomitoxin - 0.5 to 30 ppm**

**Fumonisin - 0.5 to 100 ppm**

**Ochratoxin A - No change**

**Zearalenone - No change**



# Proposal - Expand Concentration Ranges



- Increase highest concentration level in performance criteria (expand range)
- Establish %RSD to determine acceptable range
- Oct. 1-31, 2014 – Feedback from test kit manufacturers
  - Additional dilutions needed to cover expanded ranges
  - Proposed %RSD requirement at highest level too low

Mycotoxin	Current Highest Level	Proposed New Highest Level	Proposed New % RSD
Aflatoxins	100 ppb	300 ppb	14
Deoxynivalenol	5 ppm	30 ppm	6.0
Fumonisin	5 ppm	100 ppm	8.0



# Update of Performance Criteria



- **Expand concentration ranges in performance criteria**
  - Considering feedback from test kit manufacturers
- **Continue to allow supplemental analysis to report above the highest concentration specified in performance criteria (aflatoxins, DON, fumonisins)**
- **Clarify policies**
  - Multiple procedures for single test kit
  - Commodity definitions and groupings
  - Sensitivity to electromagnetic fields
  - Use of significant figures



# DON Pilot Monitoring Program



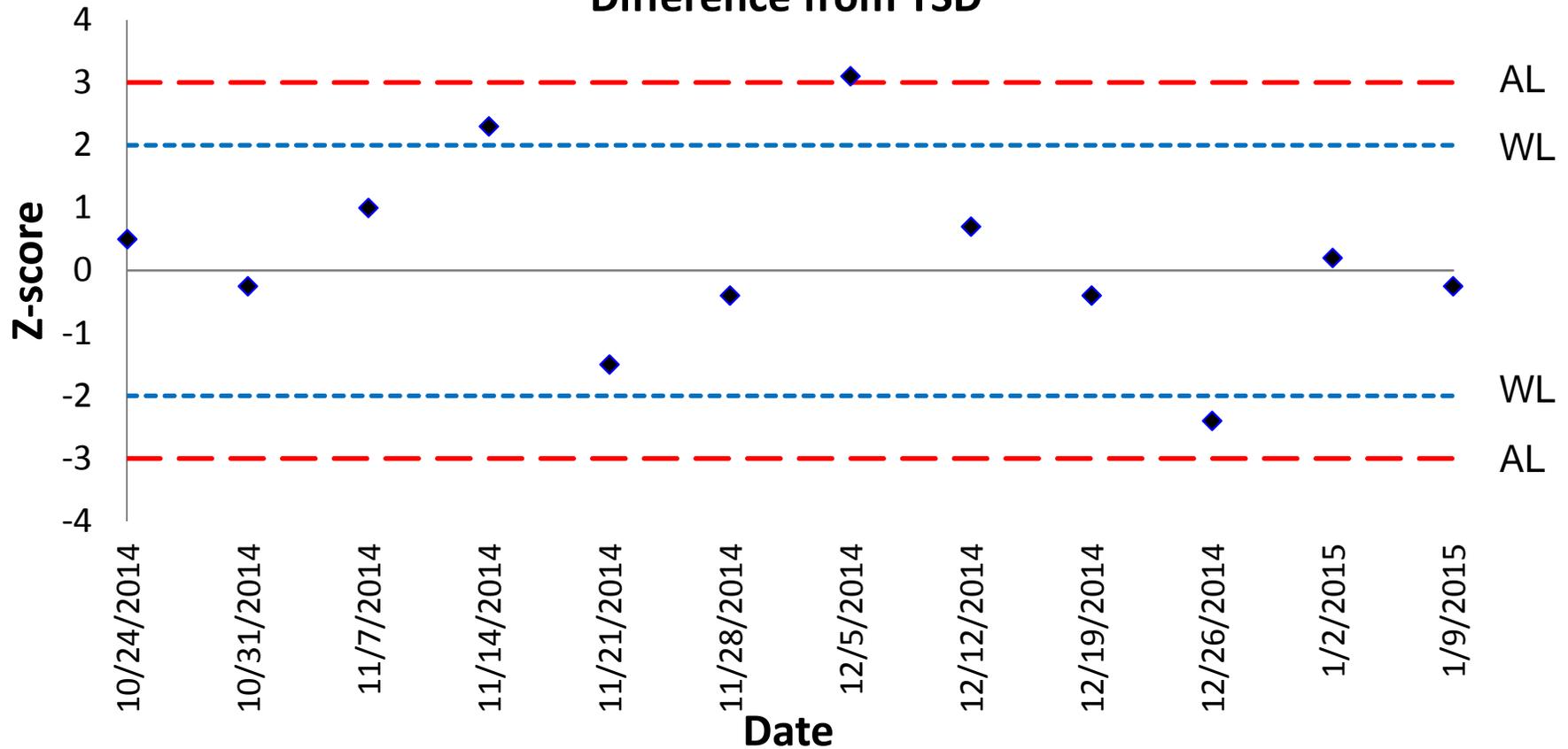
- 67 testing locations as of October 22
- Sampling
  - October 20, 2014 – April 20, 2015
  - 0.5 – 1% of official tests
  - Wheat and barley only
- Analyze by GIPSA reference method
- Results provided following week



# Inspection Monitoring Program Feedback



## Difference from TSD



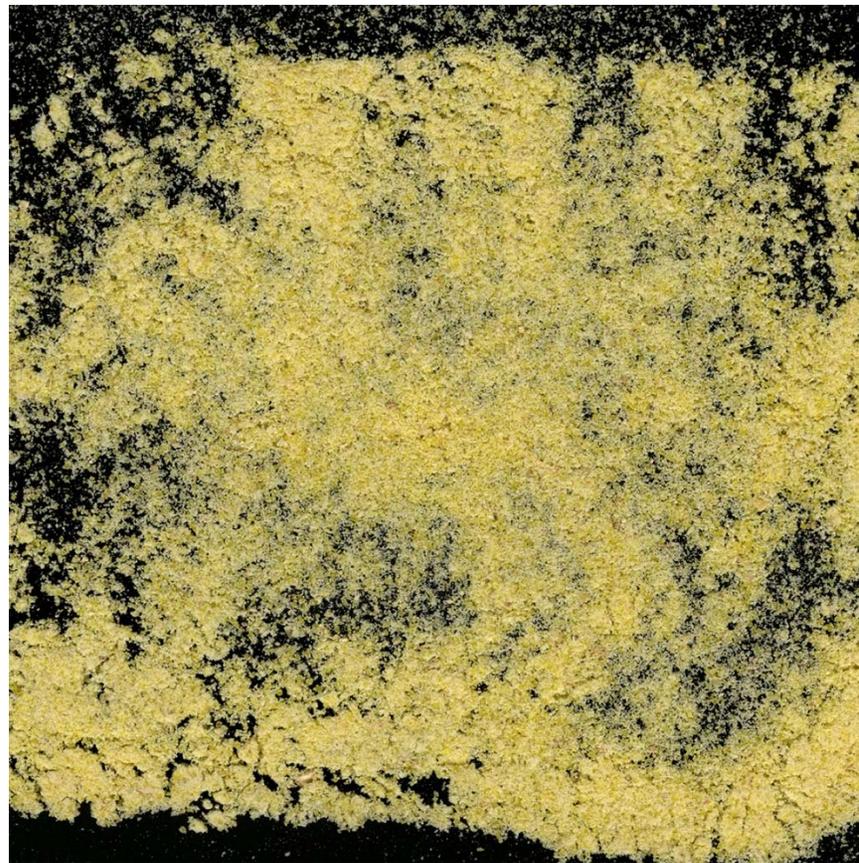
# FGIS Aflatoxin Grinding Procedure



**Coarse**



**Fine**



# FGIS Aflatoxin Grinding Procedure



- Does the current FGIS grinding procedure compromise accuracy?
- Current procedure
  - Romer Model 2A and Bunn mills
  - Optimum 60 – 75% passes U.S. Standard No. 20 sieve
  - 50% passing No. 20 sieve acceptable
- Evaluation
  - Coarseness
  - Time
  - Accuracy
  - Precision (variability)
- Can a new procedure be found that is both practical and results in a finer grind?
- Does this procedure result in more accurate and consistent results?



# Goals for FY 2015



- **Mycotoxin Test Kit Evaluation**
  - Update performance criteria
    - ✦ Expand evaluated concentration ranges (aflatoxins, DON, & fumonisins)
    - ✦ Clarify certain policies
- **DON Pilot Monitoring Program**
- **Mycotoxin Quality Assurance Program**
  - Implementation plan and directive (dependent on successful recruitment)
- **Evaluate FGIS grinding procedure for aflatoxin testing**



# Questions?

