

Mycotoxin Test Kit Program



**GRAIN INSPECTION ADVISORY
COMMITTEE MEETING
OCTOBER 27, 2015**

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Outline of Presentation



- Update on Mycotoxin Test Kit Performance Criteria
- Elimination of Qualitative Test Kit Program
- Revision of Quantitative Certification Procedures
- Conclusion



Revision of Mycotoxin Performance Criteria



- April 2015 Resolution
 - The Advisory Committee recommends FGIS move forward with expanding the mycotoxin concentration ranges to the following:
 - ✦ Aflatoxin to 5 – 300 ppb
 - ✦ DON to 0.5 – 30 ppm
 - ✦ Fumonisin to 0.5 – 30 ppm
 - At the manufacturer's request, FGIS will verify the supplemental analysis performance at the maximum range as established by the manufacturer.
- Update – new criteria expected in first quarter FY 2016



Qualitative Test Kit Evaluation Program

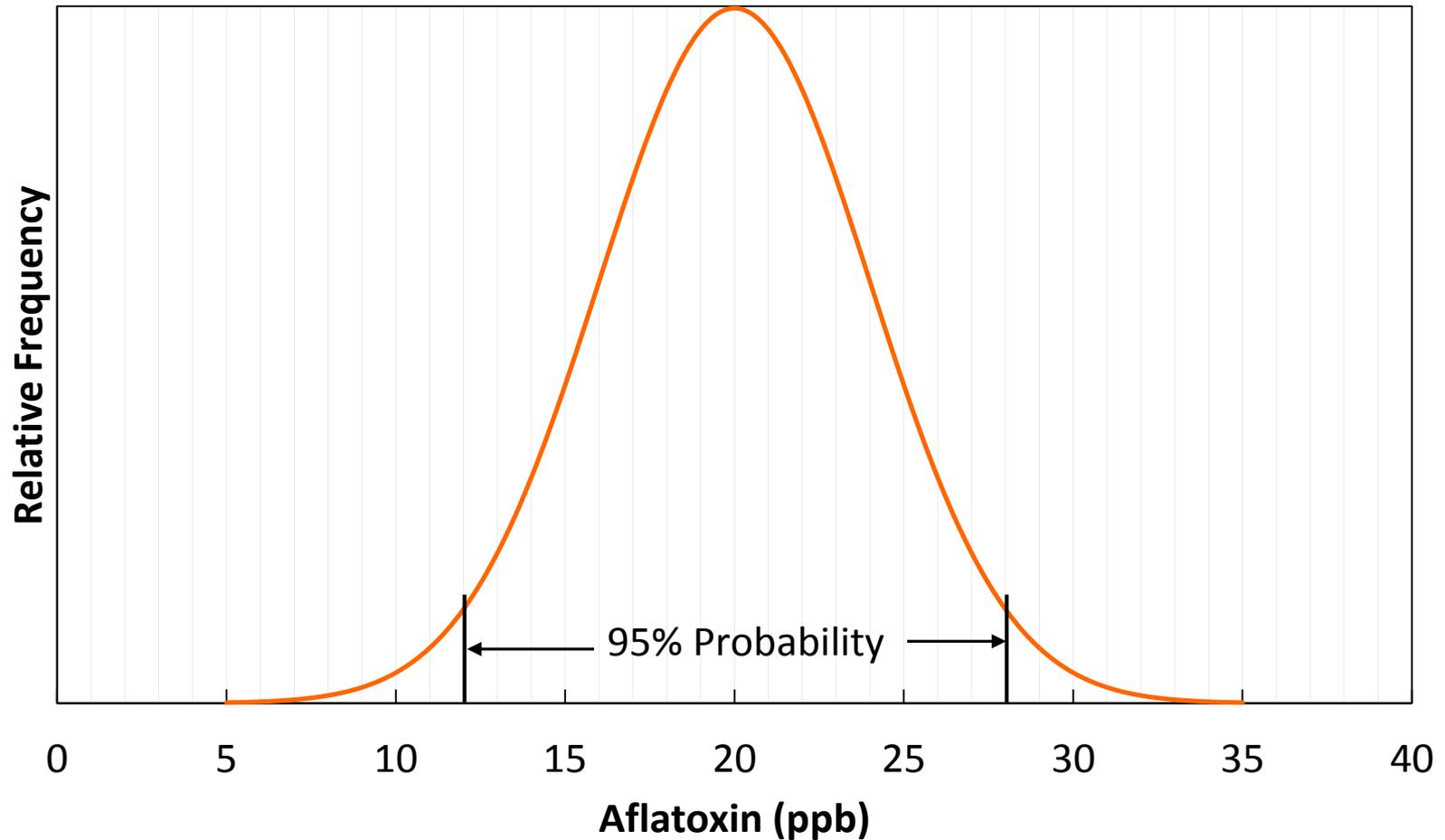


- Detection Threshold
- Manufacturer submits data
 - Three different test kit lots
 - 120 blank samples (40 per lot) → all negative
 - 120 fortified samples (40 per lot) → all positive
 - Additional samples at 15 °C and 30 °C
- GIPSA verifies performance
 - Three different test kit lots
 - 30 blank samples (10 per lot) → all negative
 - 30 fortified samples (10 per lot) → all positive
- Certificate of Performance (COP)



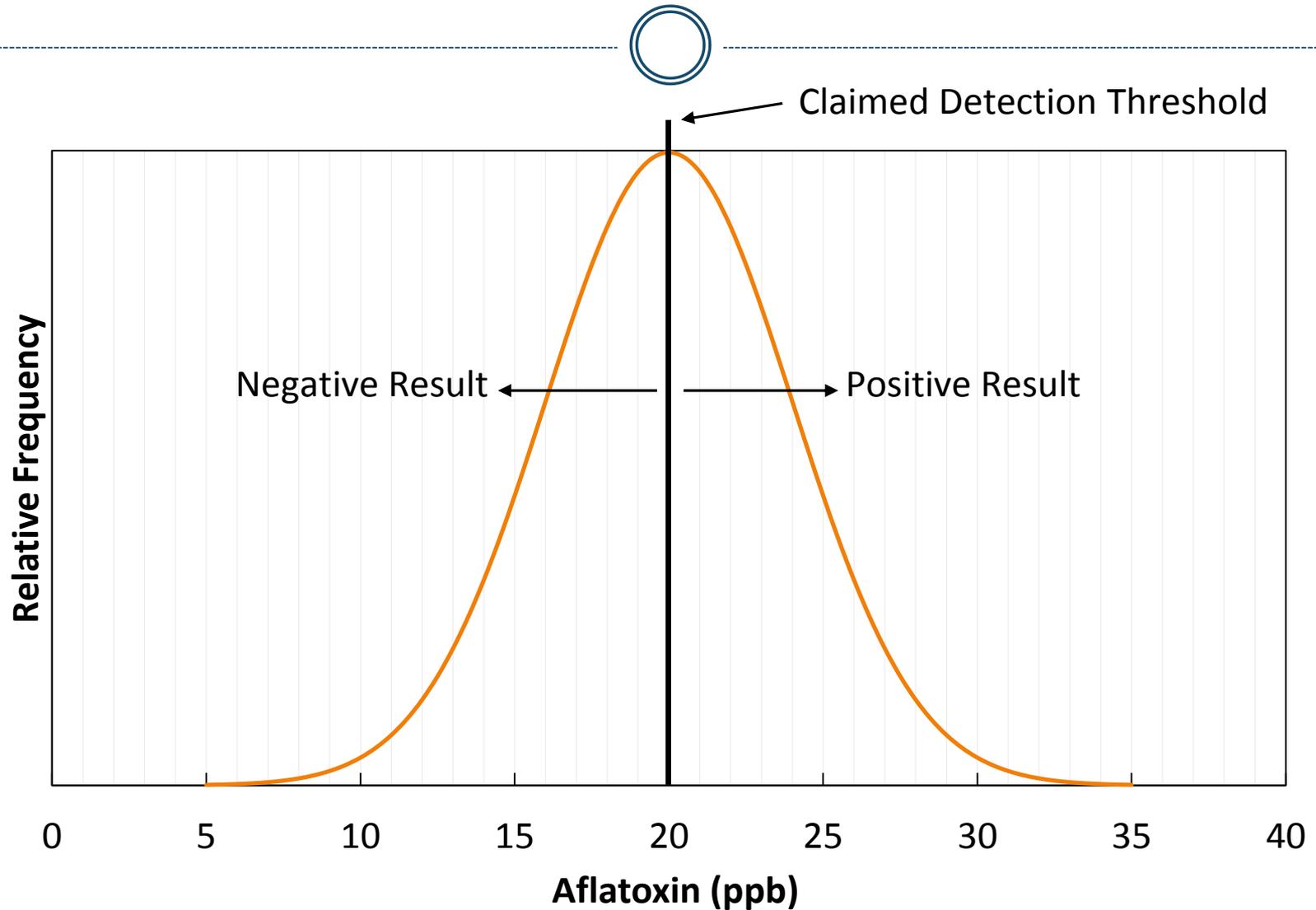
Qualitative Test Kit Example – Aflatoxin at 20 ppb

Normal Probability Distribution



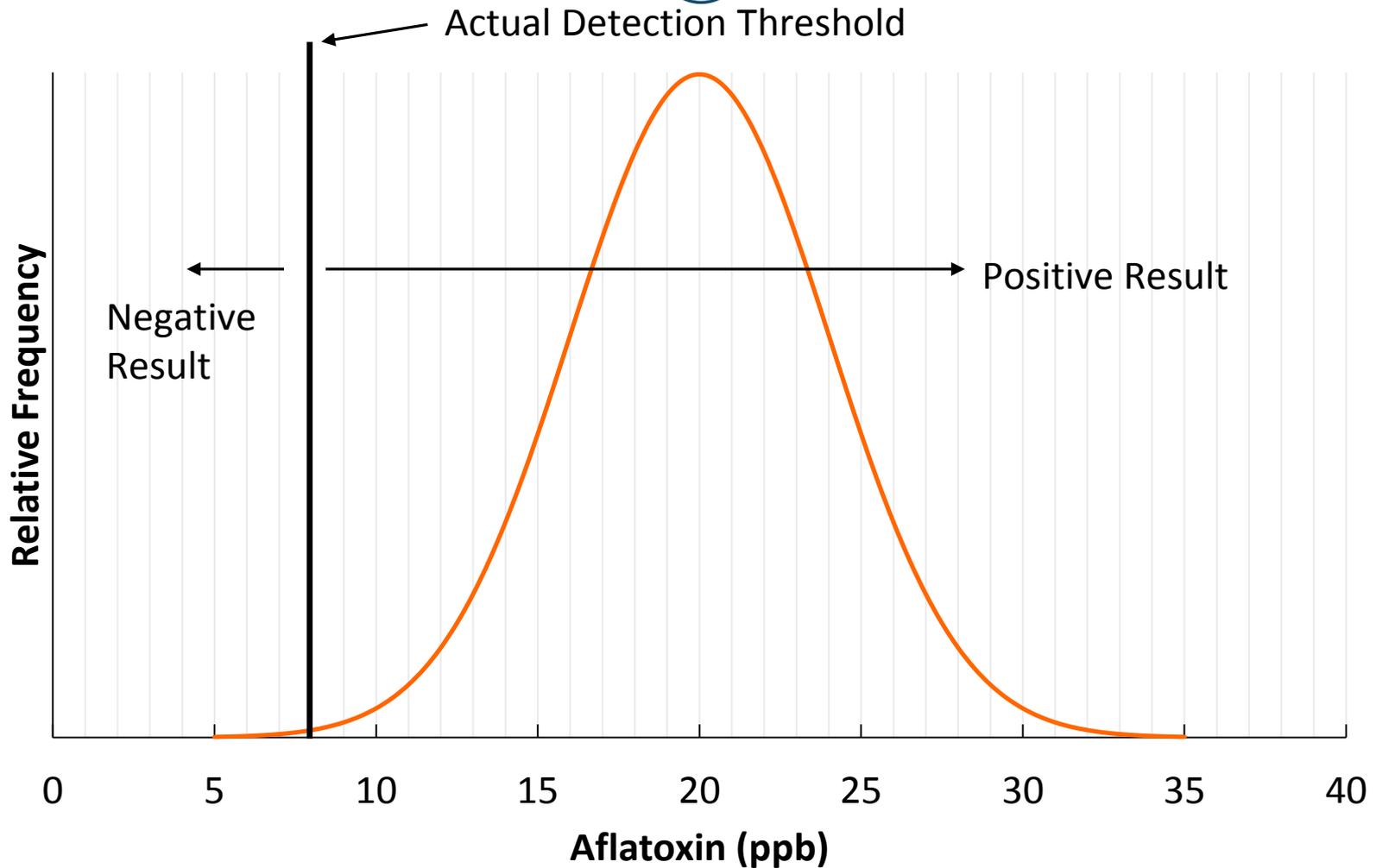
Qualitative Test Kit Example – Aflatoxin at 20 ppb

Normal Probability Distribution



Qualitative Test Kit Example – Aflatoxin at 20 ppb

Normal Probability Distribution



Qualitative Test Kit Program



- Qualitative test kits for screening only
 - Negative result < detection threshold
 - Positive result
 - ✦ Detected but may be less than detection threshold
 - ✦ Need follow up with quantitative analysis

- Proposal – Eliminate qualitative test kit program
 - Quantitative test kits are nearly as fast
 - Only 2 official testing locations are using them
 - Resources can be directed towards quantitative test kit evaluation, inspection monitoring, and training
 - No opposition from AAGIWA or test kit manufacturers



Deoxynivalenol Monitoring Inspection Program



- October 20, 2014 to present
- Accuracy of official deoxynivalenol (DON) inspections
 - Official testing locations submit wheat and barley samples to TSD
 - 1 sample per 100 tested each week
 - Compared to GIPSA reference method
 - Weekly reports issued
- Results – as of October 22, 2015
 - 56 testing locations submitted samples
 - 1017 total samples analyzed
 - Issue with rounding results



Deoxynivalenol Inspection Monitoring Program



- Current certification procedure for DON
 - Round to nearest whole ppm
 - Excessive rounding error → inflated bias
- More precision should be used

Detector Reading (ppm)	Certified Value (ppm)	Rounding Error (%)
0.55	1	82
1.43	1	-30
2.25	2	-11
4.45	4	-10

Current Certification Procedures



- Round to nearest whole ppb
 - aflatoxins, ochratoxin A, zearalenone
- Round to nearest whole ppm
 - DON, fumonisins
- Excessive rounding error for aflatoxins, DON, ochratoxin A, and fumonisins



Recommended Certification Procedure



- **Certify to 2 significant figures as default**
 - Used in test kit evaluation program
 - Take advantage of test kit precision
 - Avoid loss of significant information
 - Use same procedure for all mycotoxins
- **Allow option for applicant to request certification to whole number**



Recommended DON Certification Procedure



- Current procedure → excessive rounding error
- Recommended procedure → rounding error < 5%

	Current			Recommended	
Reading (ppm)	Certified Value (ppm)	Err (%)		Certified Value (ppm)	Err (%)
0.55	1	82		0.55	0
1.43	1	-30		1.4	-2
2.25	2	-11		2.3	2
4.45	4	-10		4.4	-1



Conclusion



- Recommend eliminating qualitative test kit program
 - Proposed effective date - December 31, 2015
 - Phase out qualitative test kits as COPs expire
- Recommend revising certification procedures
 - Use two significant figures as default
- Seek Grain Inspection Advisory Committee resolutions



Questions?

