Mycotoxin Monitoring in the Age of the Food Safety Modernization Act (FSMA) – Fit For Purpose Strategies and Solutions

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A Brief History of Mycotoxins

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Our History in the Food Industry

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- VICAM launched its first product in 1987 – AflaTest
- Aflatoxin outbreak impacted poultry/egg production
- Specialization in antibody-based diagnostics and laboratory sample prep
- Our First Work: Enable prevention and confirmatory testing for mycotoxins on-site or in the food and agricultural laboratory.

Mycotoxin Testing & Management Through The Years

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1985

AflaTest for fluorometer & LC

1995

Multiple mycotoxin IA columns launched

2006

VICAM acquired by Waters Corporation

Waters
THE SCIENCE OF WHAT'S POSSIBLE.®

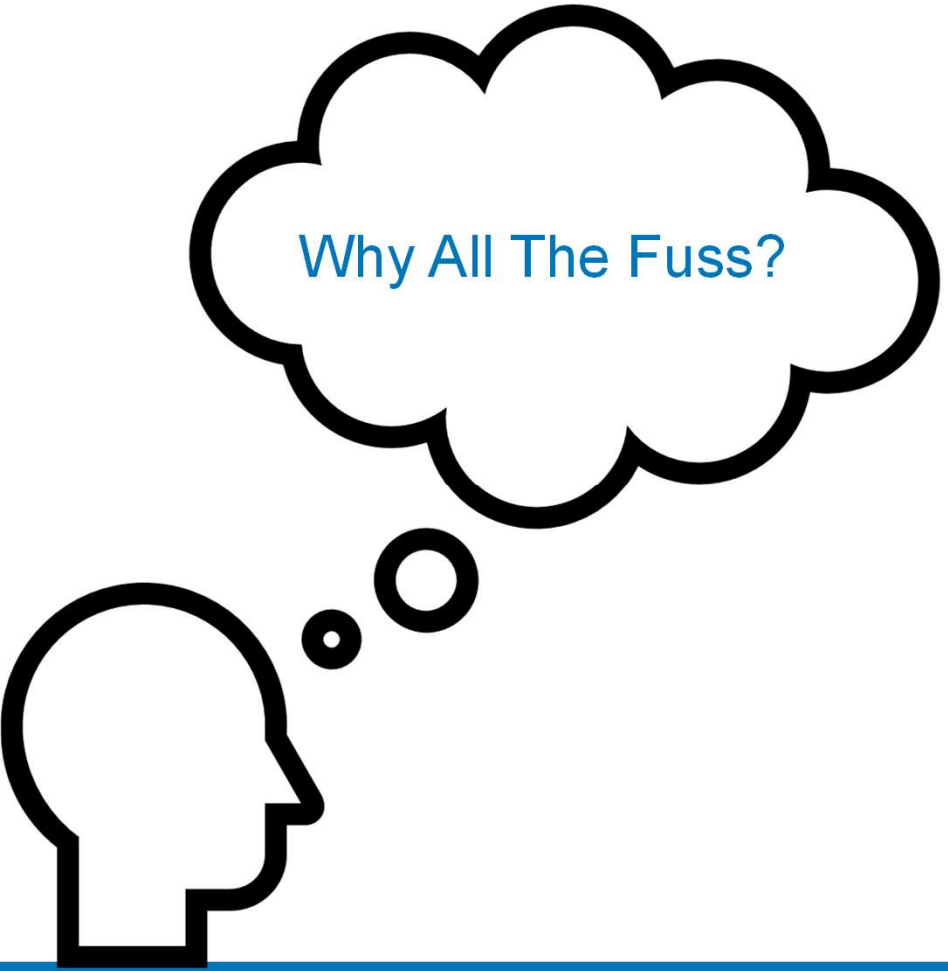
2010

Vertu quantitative lateral flow test strips launched

2019

2021

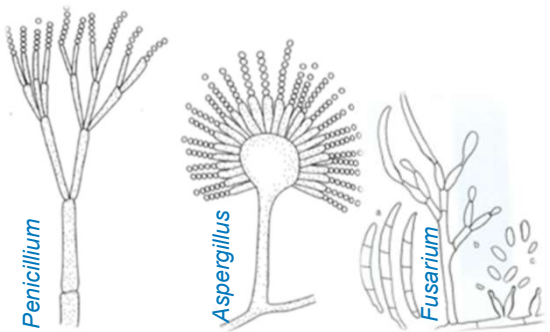
…and beyond



You Might Be Thinking...

- How Important Are Mycotoxins Really?
- Where Do They Come From?
- Are Mycotoxins Invisible?
- Does It REALLY Matter If/How I Test?
- Do I Have to Hire a Chemist?
- How Can I Be Sure This Test Is Working?
- How Often/How Many Tests Are Enough?
- Can I See Mycotoxins in Inbound Corn or Finished Masa/Tortillas?

What are mycotoxins?



Fumonisin

Zearalenone

Aflatoxin

Citrinin

T2/HT-2

Deoxynivalenol

Ochratoxin A

Food & Agricultural Products Affected by Mycotoxin Contamination

- Tree Nuts
- Peanuts
- Grain
- Wine
- Coffee
- Flour Milling
- Cereals
- Feed
- Oats
- Ethanol
- Dairy
- Rice
- Botanicals
- Spices
- Snack Foods
- Pet Food
- Hemp/Cannabis

						
Mycotoxins	**AFLATOXINS B1, B2, G1, G2, M1**	**DEOXYNIVALENOL**	**FUMONISINS B1, B2, B3**	**OCHRATOXIN A**	**T-2/HT-2**	**ZEARALENONE**
Selected Molds That Produce Toxins	*Aspergillus flavus, Aspergillus parasiticus*	*Fusarium graminearum*	*Fusarium verticillioides*	*Aspergillus ochraceus Penicillium verrucosum*	*Fusarium and other mold species*	*Fusarium graminearum*
Foods Susceptible to Contamination	Maize, groundnuts, nuts, cottonseed, copra, spices, milk, wheat, oats, barley, and rice	Maize, wheat, barley, malted barley, and oats	Maize and other cereal grains	Maize, wheat, barley, beer, oats, sorghum, dried vine fruits, wine, coffee, and cocoa	Maize, wheat, barley, oats, rice, sorghum, and other cereal grains	Maize, wheat, barley, grain, and sorghum
Health Effects	▪Liver cancer and damage ▪Immunosup-pression ▪Decreased milk and egg production	▪Damage to digestive tract, bone marrow, spleen, reproductive organs ▪Weight loss, vomiting, and feed refusal	▪Cancer in rats ▪Brain decay in horses ▪Lung congestion in pigs ▪Human Esophageal Cancer	▪Kidney damage and cancer ▪Immunosup-pression	▪Skin and oral lesions in livestock and humans ▪Alimentary toxic aleukia in humans ▪Considered 10x more toxic than DON	▪Negatively impacts reproduction, fetal development, and the health of newborns ▪Causes feminization in animals at 1 ppm

Mycotoxin Monitoring from Field to Market: Where is the Need?

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- Field
- Storage/Processing/Transport
- Market

Mycotoxins in Grains and Other Food Products – Why Testing Matters

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"The presence of mycotoxins in commodities is presently unavoidable and, therefore, to avoid their occurrence in the food chain requires management strategies that would prevent contaminated commodities from entering food and feed processing facilities. Testing of the commodities is required to accomplish this process."

– The Council for Agricultural Science and Technology report #139, 2003

Mycotoxins: Economic and Health Risks

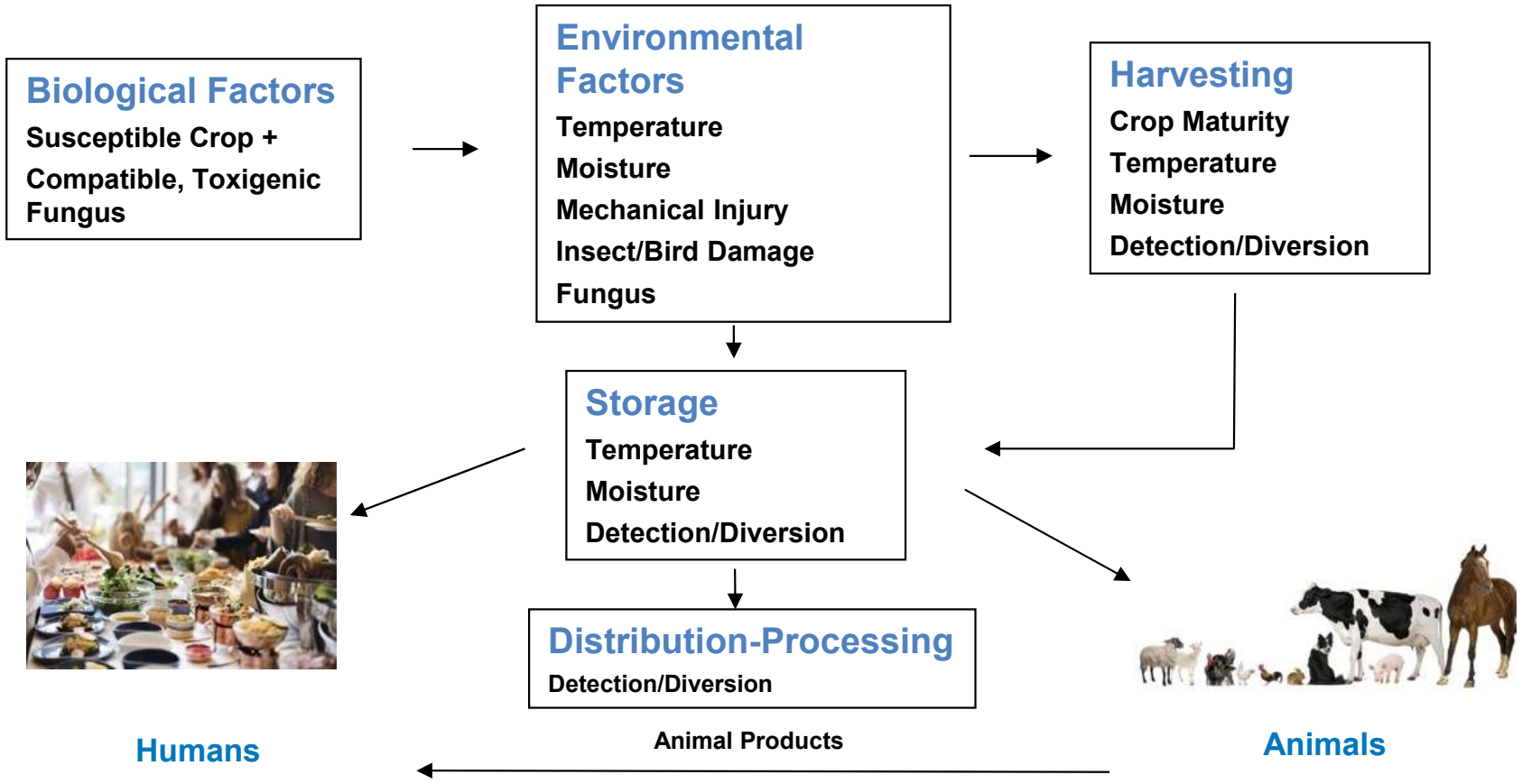


Figure 6.1. Factors affecting mycotoxin occurrence in the food chain (Pestka and Casale, 1989) from CAST report 1989.

When Should I Suspect Mycotoxins?

- Weather conditions…..
- Where did my ingredients come from???
- How was it stored???

Food & Agriculture Mycotoxin Monitoring

Harvest

- Screening
- Confirmation

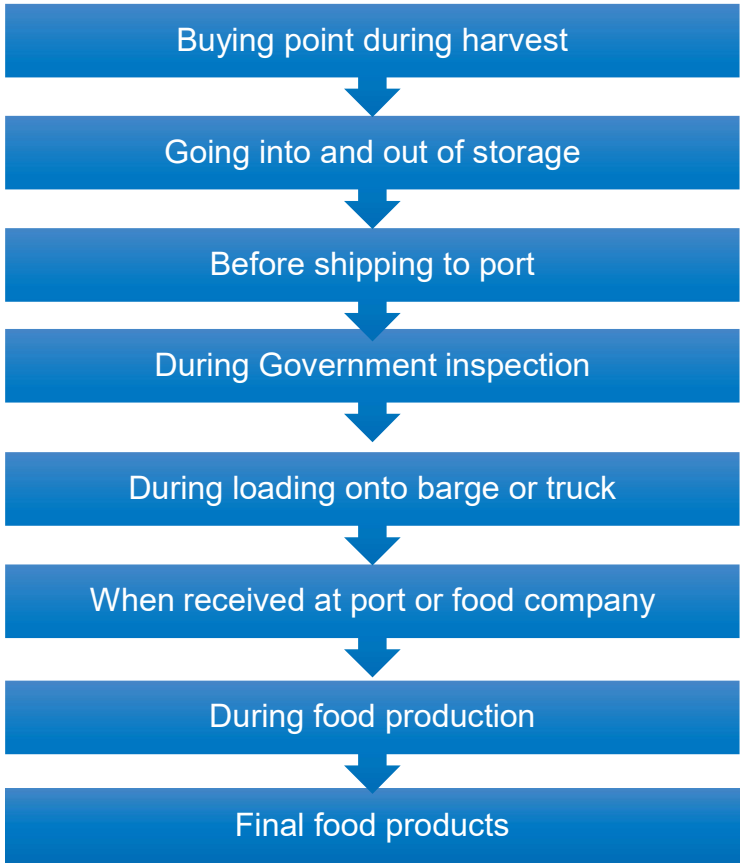
Storage

- Segregation
- QC Before Processing

Finished Products

- Laboratory QC
- Prior to Export or Import

Points where mycotoxins are tested



Worldwide regulation of Mycotoxins

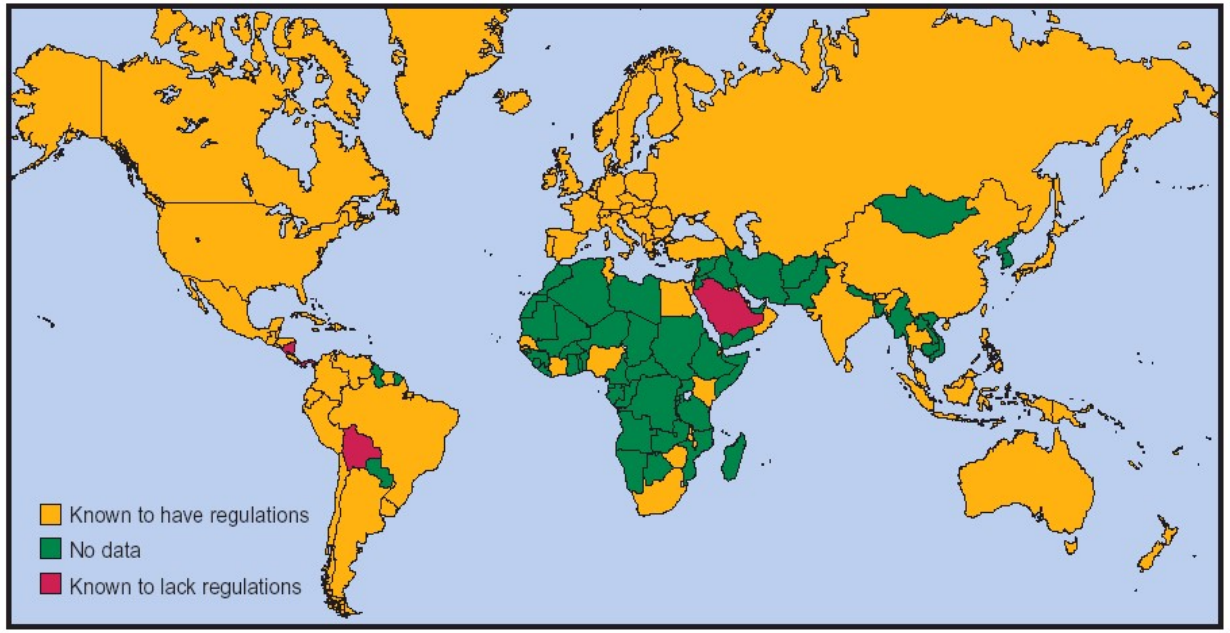


Figure 8.1. Counties known to regulate mycotoxins in food and feed (yellow), those where it is unknown whether regulations exist (green), and nations known to have no specific regulations (red) (Food and Agriculture Organization 1997).

(CAST report, 2003)

FDA Regulatory Limits – Aflatoxin

Action Level	Commodity	Species
0.5 ppb {Aflatoxin M1}	Milk	Humans
20 ppb	Any Food	Humans
20 ppb	Feed	All species of animals
Exceptions:		
100 ppb	Corn	Breeding Cattle, breeding swine , and mature poultry
200 ppb	Corn	Swine
300 ppb	Corn	Beef Cattle
300 ppb	Cottonseed meal used in feed	All species of animals

FDA Advisory Levels – Other Mycotoxins

Mycotoxin	Levels	Commodity
Fumonisin (B1 + B2 + B3)	2,000 ppb (2.0 ppm)	Degermed, dry milled corn products (flaking grits, corn grits, corn meal and corn flour with fat content ≤ 2.25 %)
	3,000 ppb (3.0 ppm)	Popcorn
	4,000 (4.0 ppm)	Dry milled corn bran, whole or partially degermed dry milled products (flaking grits, corn grits, corn meal and corn flour w/ fat content ≥ 2.25%)
Patulin	50 ppb	Apple Juice, apple juice concentrate, apple components in processed foods
Deoxynivalenol (DON)	1,000 ppb (1.0 ppm)	Finished wheat products
Zearalenone & Ochratoxin A	No Active Regulatory Limits or Guidance	Corn, wheat, barley, rice, millet, finished feed or pet food

Designing A Preventive Monitoring Strategy

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1 AWARENESS

- How do I know if I have a problem with mycotoxins in my facility?
- FDA-FSMA: food manufacturers must assess risk, plan for monitoring and managerment for raw materials suppliers and products
- Identifying credible sources of information for risk assessment and ongoing routine testing

2 REACTION

- Where do I go to find information on testing of mycotoxins?
- Which mycotoxins should I be testing in my inbound raw materials stream?
- Which testing approach, or combination of them, best serves our operation?

3 GAME PLAN

- How often testing occur?
- Do I have the right staff and know-how to perform these tests?
- SOP to ensure consistent action for each potential mycotoxin risk for raw materials, processing and finished products.

4 IMPLEMENT

- Research test kit options and evaluate suitability for each facility.
- Select, set up, train and routinely test where needed – may adjust based on risk factors
- Establish data handling protocols, ongoing test performance review.
- Prepare for relevant auditing/governance Governing bodies.

Considerations when choosing a testing strategy

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- Time of Analysis
- Labor -Training required- appropriate level of education
- Cost - Capital investment and consumables
- Testing environment- laboratory or in the field
- Is an Official Method required? If so, what agency?
- Precision, accuracy and limit of detection needed for the method
- Information content – qualitative or quantitative, total toxin vs individual toxins

Technologies for Analysis of Mycotoxins

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Lower complexity and cost Less information

Higher complexity and cost More information

Qualitative Strip tests

Quantitative Strip tests or Immunoaffinity columns with Fluorometer

HPLC or UPLC

LC-MS UPLC-MS-MS

Rapid Detection: Field, Process & Laboratory Approaches

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- Immunoaffinity Columns with Fluorometer
  - Wide dynamic range (0-1,000 ppb Aflatoxin)
  - AOAC & USDA-GIPSA Certified Methods

- Qualitative Strip Tests
  - Quick screening
  - Simple procedure
  - Yes/No visual indication

- Quantitative Lateral Flow Strip Tests
  - Fully Quantitative
  - USDA-GIPSA Approved Methods
  - Sustainable, simple and solvent-free extraction
  - Single Extraction for analysis of up to 5 mycotoxins

What's New In Lateral Flow Strip Testing?

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- Pairing high-performance technologies
- 30-Second extraction (75% time savings)
- Simple, Secure Data Handling
- Single & Multi-mycotoxin monitoring with one water-based extraction

Characteristics of Qualitative strip tests

- Can be used in a field environment with no electricity
- Quick- Less than 5 minutes
- Easy- Anyone can be trained quickly to run the test
- Inexpensive
- Good for sorting products in field
- Visual result/reading

- Will not give exact number value

AflaCheck

DONCheck

Characteristics of Quantitative strip tests

- Can be used in a field environment
- Quick- Less than 10 minutes to test 6 mycotoxins
- Will give a number reading
- Easy- Anyone can be trained quickly to run the test
- Inexpensive
- Good for sorting/segregating inbound grains/tree nuts/peanuts

- Some strips must be refrigerated
- No dishes to wash- everything disposable
- Lower precision (variability) than instrumental methods.
- USDA-FGIS methods available

Optimizing For Multi-Mycotoxin Testing

One Extraction Enables up to 6 Different Toxins to be Tested

- Ideal for incoming raw materials
- Select only the toxins you are targeting
- Apply 100 uL of filtered extract to each strip
- Results for **up to** 6 toxins in less than 10 minutes

Characteristics of Immunoaffinity Column Methods

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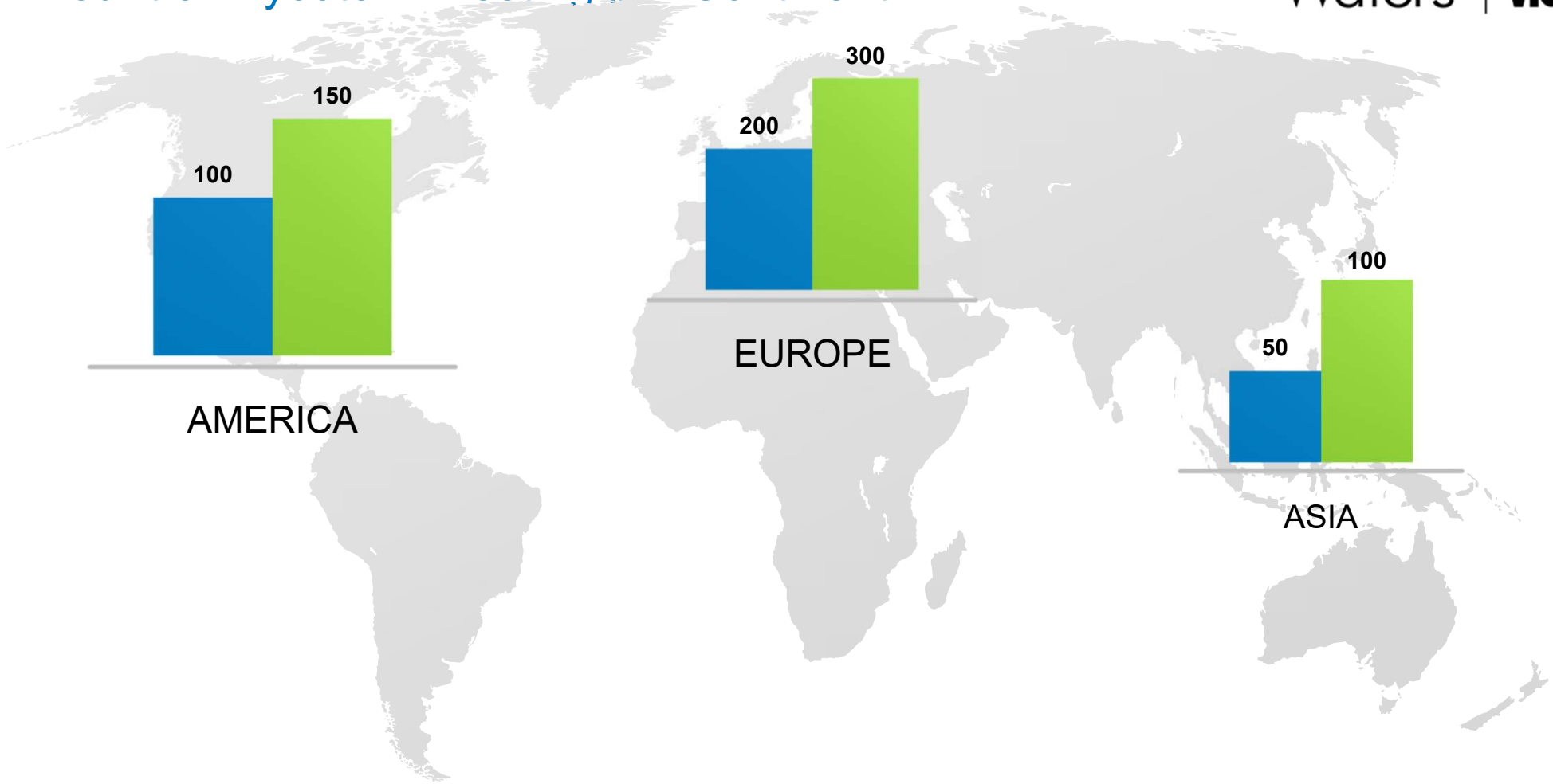
- Suitable for field or laboratory
- Quick- 5-15 minute sample prep, then detection
- Will give a number reading
- Simple to Use
- Employs fluorometer on-site or LC, LC-MS/MS for higher sensitivity
- Single or multiple mycotoxin detection simultaneously

- Long Shelf Life
- Uses organic solvents for extraction
- AOAC and USDA-FGIS methods available

Amount of Mycotoxin Testing per Continent



Technologies: Which Approach Makes the Most Sense?

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Instrumentation cost
Training required
Precision and accuracy
Information content
Versatility

Lower **Higher**

Strip tests

IAC + Fluorometer
ELISA
Fluorescence Polarization
Biosensors
Immunochemical methods

TLC HPLC, GC

LC-MS
UPLC-MS
SFC

Instrumental methods

Talk to us…

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We love to chat.

Try our mycotoxin regulations tool at www.commodityregs.com