

The Need for Speed: All-in-One Extraction Method Opens the Way to Faster Time-to-Results for Food and Feed Industry Stakeholders

Mycotoxins: The coevolution of a food safety issue and a business challenge

INTRODUCTION

For many sectors of the food and feed industry, frequent mycotoxin testing is a double-edged sword. This widely recommended practice promises to slash their risk of rejected shipments and recalls, but also threatens to cut significant chunks of time and money from their production resources. The industry's quest to balance quality and safety assurance with economy and efficiency has always posed challenges, but in the context of an increasingly globalized food supply, rising concern about foodborne illness, and intensifying competitive pressures, the need for mycotoxin test methods that help companies do more with less has taken on a new urgency.

The issues surrounding testing for these microscopic fungal metabolites first emerged in 1969, when the U.S. Food and Drug Administration (FDA) established its first mycotoxin action level of 20 ppb for aflatoxins, eight years after scientists had identified this pervasive food and feed contaminant and superpotent liver and kidney toxin as the culprit in an epidemic of acute toxicosis that killed more than 100,000 fowl. Since that time mycotoxin researchers have amassed a substantial body of data on the potential health implications of not only aflatoxins but also other mycotoxins commonly found in the food and feed chain. Scientists currently recognize more than 400 of these naturally occurring toxic contaminants and estimate that about a dozen groups of chemically related mycotoxins present health risks to humans and animals.¹ According to the World Health Organization (WHO), the most commonly observed and potentially harmful of these are aflatoxins, ochratoxin A (OTA), fumonisins, deoxynivalenol (DON, vomitoxin), zearalenone (ZEA), and patulin.² In addition to causing potentially fatal illnesses when consumed in high doses, these mycotoxins are strongly linked to cancer, organ damage, chronic immunosuppression, and other serious medical problems when ingested in minute amounts over the long term. Their negative impact on crop yield, animal productivity, and the value of agricultural commodities also threatens local and national economies, trade relationships, and the safety and abundance of the global food supply.

In response to growing awareness of these human and economic costs, mycotoxin limits in various countries around the globe have continued to multiply in number, expand across a widening range of mycotoxins and commodities, and shrink to ever lower levels. Within this evolving regulatory landscape, the success of food and feed companies at every stage of the production chain increasingly depends on continuous improvement in mycotoxin test methods. The real-world value of these testing innovations in turn hinges on not only their sensitivity and accuracy, but also their capacity to deliver credible numerical results without interrupting a company's workflow, reducing its productivity, or depleting its budget.

WHY TEST FOR MYCOTOXINS?

At first glance, the business costs of frequent testing may strike some industry stakeholders as a roadblock to their bottom line goals. Companies may worry that taking the time to routinely test every incoming shipment or storage bin could jeopardize delivery dates and production schedules. The need to choose between either absorbing testing costs or passing them along to customers tends to further dampen their enthusiasm for meticulously tracking mycotoxin levels, especially when budget and work force resources are already stretched.

Yet today's food and feed companies stand to benefit as much from exercising vigilance over mycotoxin levels as they do from answering their customers' call for decreased time-to-market and competitive pricing. For an industry whose success increasingly depends on the efficiency and credibility of global supply chains and the growth of international markets, comprehensive data on mycotoxin levels has become a non-negotiable requirement of doing business. The ability to verify the quality and safety of raw materials from local and overseas suppliers is as important to a company's reputation and profitability as the timely arrival of those materials at each successive stage of the value chain. Test data that documents a shipment's compliance with mycotoxin limits is crucial not only to gaining access to today's most lucrative markets, but also to reassuring the discriminating buyers and consumers in those markets that the seller's goods are worth the asking price.

While regulatory enforcement policies can vary significantly by commodity and trade region, the value of compliance as a risk protection strategy is hard to overstate. The legal and financial repercussions of compliance failures can be severe, widespread, and long lasting. The FDA can use noncompliant mycotoxin levels as evidence in lawsuits claiming that a company's products pose a serious public health threat. Products that exceed recommended levels may also be declared adulterated and unfit for purpose by local and overseas buyers, state officials, and custom inspectors. Whether a shipment is impounded, downgraded and diverted to a less profitable market, or banned from sale entirely, the seller faces multiple losses. In addition to its financial investment in the product, the company may lose the trust and goodwill of its buyers, potentially motivating current customers as well as new prospects to take their business elsewhere.

With the passage of the Food Safety and Modernization Act (FSMA), the FDA has gained the authority to enforce tougher sanctions for food safety violations, including mandatory recalls of products that they suspect harbor dangerous levels

of contamination. The act also incorporates legally binding Hazard Analysis and Risk-Based Preventive Controls (HARPC) rules that require the implementation of proactive measures to minimize food safety hazards, including chemical contaminants such as mycotoxins. Among such measures, testing raw materials in the field and at shipping points is recognized in these rules as a highly effective means of preventing the spread of contamination to downstream locations such as storage facilities and manufacturing plants, where the financial and legal ramifications of compliance failures become more serious. By segregating contaminated lots before they enter the final stages of the production stream, sellers and buyers alike dramatically reduce the risk of bearing responsibility for foodborne illness outbreaks and for financial losses from the destruction of manufactured products.

GROWING KNOWLEDGE OF MYCOTOXINS FUELS TOUGHER COMPLIANCE DEMANDS

While the advent of rapid immunoassays such as antibody-coated strip tests has greatly improved the speed and affordability of frequent on-site monitoring, the need to continuously adapt the testing process to changing quality and safety standards remains. To meet the rising bar set by today's regulators, buyers, and consumers, many industry sectors now have to verify compliance with maximum limits for an expanding range of mycotoxins. This challenge reflects the insidiousness of the threat that mycotoxins pose to the food chain. A growing body of research indicates that mold-susceptible crops, including grains, coffee, nuts, and spices often harbor a mix of mycotoxins that become significantly more potent and harmful when they occur together. For example, studies of mycotoxin co-occurrence conducted in Europe over the last two decades reported that 75 to 100 percent of feed samples contained levels of two or more mycotoxins that could negatively affect animal health and performance.³ Evidence that traces of various co-occurring mycotoxins remain in the meat, milk, and eggs of animals that consume contaminated feed extends the troubling implications of these studies to the public health arena.

Once mycotoxin mixtures get into a commodity, they're virtually impossible to eliminate entirely. The usual decontamination strategies, including mold removal and heat processing often leave unsafe levels of co-occurring mycotoxins behind. Furthermore, processes such as milling and distilling that tend to reduce mycotoxin content in food and beverages for humans can actually concentrate the contamination in the fraction of grain typically used in animal diets. Studies confirm the resulting impact on the quality of

feed and pet food ingredients can be quite substantial. For instance, a 2016 report cited a threefold increase in mycotoxin levels in distillers' dried grains with solubles (DDGS) compared to the starting corn.⁴ A later study that found evidence of the same phenomenon in wheat byproducts such as bran and middlings reported levels that were up to eight times higher than in the wheat they were derived from.⁴

MULTI-MYCOTOXIN CONTAMINATION: IMPLICATIONS FOR THE CORN INDUSTRY

These issues are especially relevant for corn growers and their downstream customers. As the source of products and byproducts ranging from corn flour, corn oil, corn starch, and corn sweeteners to corn meal, corn bran, and DDGS, corn is one of the most widely used ingredients in the food and feed industries. "Corn is uniquely susceptible to the broad range of major mycotoxins from aflatoxins to ochratoxin A, fumonisins, deoxynivalenol, and zearalenone," said Lingyun Chen, Director of Research and Development at the Massachusetts-based test developer VICAM,[™] A Waters Business. He noted the implications of this fact for the company's corn sector customers. "While aflatoxin monitoring used to be sufficient to satisfy regulatory, contractual, and internal QC demands back in the early days of mycotoxin control efforts," said Chen, "companies may now need to run as many as five different mycotoxin tests to ensure their products pass muster."

The need to provide inspectors and customers with detailed mycotoxin profiles spans corn buyers and sellers in every market sector. Data on multiple mycotoxins is becoming increasingly important to the public perception of corn-based products consumed by populations with increased sensitivity to their effects, such as breakfast cereals and snack foods marketed to young children. The high risk of concentrated levels of multiple mycotoxins in corn byproducts and co-products is driving demand for comprehensive mycotoxin tracking in the feed and pet food sectors as well. As the major providers of corn DDGS, ethanol plants also have a vested interest in supplier and internal data on the full spectrum of fungal contaminants that could undermine their co-products' acceptability as feed ingredients.

AN EXTRACTION METHOD FOR FAST TIMES: CLEARING A MAJOR WORKFLOW BOTTLENECK

Even though strip tests can deliver results in as little time as 10 minute, the need to repeat the test not only in multiple product lots but also for multiple mycotoxins can stretch that brief process into a significant delay. To minimize that time lag, any potential bottlenecks in the test process must be identified and addressed. Chen explained that most serious obstacle to

the efficiency of on-site testing has always been the extraction step. "From a technical standpoint, the extraction procedure for our strip tests is actually quite simple and straightforward, he said. "but it's the step that requires the most hands-on time and attention to the instructions to perform correctly."

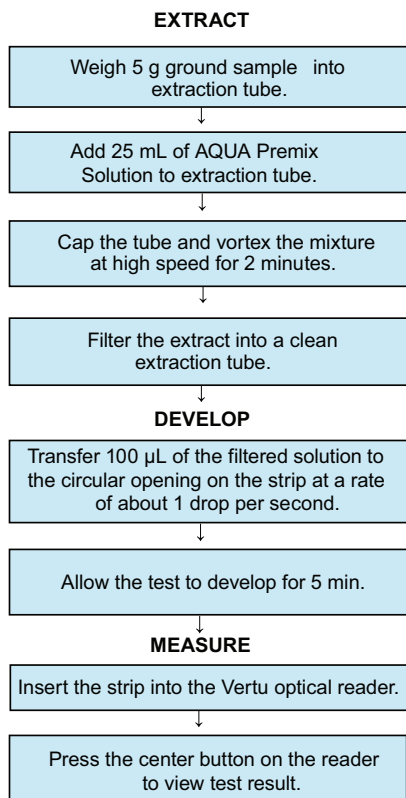
Patricia Jackson, VICAM's Market Development Manager, noted that the company's Vertu AQUA strip test line features an optimized extraction procedure that helps companies not only break through this common barrier to efficient workflow but also reduce the overhead costs of testing for multiple mycotoxins. "Companies can now use the extract from one sample to measure all the major mycotoxins of concern with five different strip tests," she said. The line comprises the [Afla-V[™] AQUA](#), [Ochra-V[™] AQUA](#), [Fumo-V[™] AQUA](#), [Zearala-V[™] AQUA](#) and [DON-V[™]](#) kits. "The use a single extract to test for two or more mycotoxins empowers companies to avoid production and delivery delays without compromising quality control while simultaneously enjoying substantial savings on the cost of labor and test materials," said Jackson.

The highly sensitive monoclonal antibodies embedded in the strip tests enable growers, processors, storage facility operators, and manufacturers to obtain accurate quantitative results at or below recommended limits without sending samples out for laboratory analysis. The user-friendly tests are the most economical and practical choice for situations that demand real-time decision-support data, such as routine QC checks at mills and grain elevators, determining the acceptability of product lots at shipping points, and prescreening samples in high-throughput laboratories. VICAM's USDA-GIPSA approved Afla-V AQUA test can also be used to officially certify compliance with the FDA action level for aflatoxins. Users don't need any special training to perform or interpret the tests (see diagram below). Numerical results are clearly displayed on the digital screen of a portable optical reader and can be printed for immediate hand-off to inspectors or internal personnel or transferred to an Excel spreadsheet for tracking quality trends.

Jackson noted another important advantage of the line for food and feed businesses seeking to maximize the financial and environmental sustainability of their frequent testing programs: "The water-based extraction procedure eliminates the expense and environmental hazards of purchasing, storing, and disposing of toxic organic solvents." All these benefits add up to a major boon for businesses striving to adapt to the both current regulatory climate and an increasingly competitive marketplace. "Thanks to the development of a time- and money-saving extraction procedure," said Jackson, "companies no longer have to

choose between a lean, fast-paced operating environment and strict compliance with today's rising quality and safety standards. For those that take advantage of continuing advances in rapid test methods, protecting human and animal health while building their bottom line is a realistic goal."

1 Extraction x 5 Strip Tests = Levels of 5 Different Mycotoxins in <1 Hour



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