

## Managing the Bottom-Line Impact of Ochratoxin A Limits on the Coffee Value Chain

### OCHRATOXIN A: CAUSES AND EFFECTS OF A NATURALLY OCCURRING TOXIN

The natural toxic contaminant ochratoxin A (OTA) poses an ongoing threat to the marketability and value of coffee at every step of its journey to market. For growers and exporters in major coffee-producing regions<sup>1</sup>, this risk literally comes with the territory. The tropical and subtropical climate zones that favor cultivation of the two dominant coffee varieties, Arabica and Robusta, also encourage the growth of several species of *Aspergillus* molds that produce this potent mycotoxin. These toxigenic molds can infect pre-harvest coffee cherries and tend to become more prevalent during harvesting, fermentation, drying, and storage of green coffee beans. Factors that can increase the chances of rapid mold growth include insect and mechanical damage, weather extremes such as droughts and floods, and failure to adequately dry beans before shipping. The risk of widespread contamination persists even after crops enter the cooler climates of the top three coffee-importing regions. In the European Union and the United States, *Penicillium verrucosum*, an OTA-producing mold that inhabits temperate zones, can gain a foothold in green coffee with high moisture content or physical defects, especially when stored or transported under damp conditions.

**Table 1: Top 10 Coffee-Exporting Countries in 2016<sup>1</sup>**

Arabica Exports	Robusta Exports	Total Exports
Brazil	Vietnam	Brazil
Colombia	Brazil	Vietnam
Ethiopia	Indonesia	Colombia
Honduras	India	Indonesia
Peru	Uganda	Ethiopia
Guatemala	Malaysia	Honduras
China	Cote d'Ivoire	India
Nicaragua	Thailand	Peru
Mexico	Cameroon	Uganda
India	Laos	Guatemala

Once OTA gets into raw crops, the contamination is very difficult to remove completely. While studies show considerable variation in the degree of OTA reduction achieved by roasting, reports confirming measurable levels in finished products align with the current scientific characterization of mycotoxins as heat-resistant chemicals that can persist even after processing kills mold and other harmful microorganisms.

Although the OTA concentrations in roasted coffee may be as minute as a few part-per-billion (ppbs), evidence suggests that chronic exposure to very low OTA doses may have negative effects on human health. Proven to cause kidney damage and disease, including cancer, in all animal species tested, OTA has also been linked to kidney disease and liver damage in humans and remains under investigation as a possible human carcinogen. The health implications of OTA are further complicated by its tendency to occur in mixtures with aflatoxins and fumonisins, two groups of mycotoxins whose physiological effects are similar to those of OTA. Laboratory studies and animal research indicate that interactions between the different mycotoxins in such mixtures can dramatically increase their toxic potential, including their carcinogenicity. These interactions can result in particularly severe health risks when they occur between OTA and aflatoxin B1, one of the strongest known human carcinogens and a potent liver toxin. Researchers have found levels of aflatoxin B1 in samples of decaffeinated green coffee beans that health officials in many countries would consider significant even without the compounding effects of OTA and fumonisins.

## REGULATORY AND MARKETPLACE CHALLENGES

Concerns about these health risks are prompting a growing number of countries to expand government measures to minimize the presence of mycotoxins in the food supply by setting stringent maximum limits for OTA in coffee (see Table 2). The current EU regulations apply only to roasted and soluble (i.e., instant) coffee; however, harmonized limits for green coffee remain under consideration, and 10 countries both within and outside the EU have already set their own limits for this commodity. Although the United States has yet to establish maximum limits for OTA, the FDA is currently monitoring OTA levels in imported and domestic commodities to inform its deliberations on future control measures.<sup>2</sup> In countries where no maximum limit applies to green coffee, buyers often set their own threshold to avoid contaminating roasting equipment and reduce the risk of actionable levels of OTA remaining in finished products. As a guideline, the International Trade Centre's (ITO) *Coffee Exporter's Guide* advises against using green coffee with OTA levels that exceed 15 ppbs.<sup>3</sup>

**Table 2: OTA Regulations for Coffee Products<sup>4,5</sup>**

Country	OTA limits (ppbs)			
	Green coffee	Roasted coffee	Soluble coffee	Coffee (type unspecified)
EU member states (harmonized limits)		5	10	
Brazil		10	10	
Bulgaria	8	4		
Czech Republic	10	10	10	
Cuba				5
Egypt		5	10	
Finland	5	5	5	
Germany		3	6	
Greece	20	20	20	
Hungary	15	10	10	
Indonesia		5	10	
Italy	8	4	4	
Malaysia		5	10	
Portugal	8	4	4	
Singapore	2.5	2.5		
South Korea		<5	<10	
Spain	8	4	4	
Switzerland	5	5	5	
The Netherlands		10	10	
Uruguay				50
Vietnam		5	10	

The repercussions of coffee shipments that violate the importing country's OTA regulations extend across the supply chain, damaging business reputations and excluding products from lucrative markets. To find buyers in another market who are willing to accept the risks associated with a rejected shipment, exporters typically have to offer steep discounts, and if this strategy fails, the shipment may be destroyed at the exporter's expense. The fallout of regulatory violations is particularly far-reaching in the European Union where a failed inspection in one member state automatically triggers an EU-wide "rapid-alert" system that publicly identifies the producing country as the potential source of a food safety hazard, casting a shadow of suspicion on all coffee shipments from that region.

Since the implementation of the 2011 Food Safety Modernization Act (FSMA), intensive efforts to protect consumers from food-borne contaminants have also become the norm in the United States. With the sweeping policy changes ushered in by the new law, all FDA registered food facilities, including, coffee importing companies, roasters, warehouses, and shippers, are facing stricter scrutiny of their safety practices and harsher sanctions for lapses in their contamination control procedures.

During the first year the law was in place, the FDA inspected more than 19,000 food facilities;<sup>6</sup> nearly double the number conducted in 2001<sup>7</sup> and issued 52 percent more warning letters than it did in 2010.<sup>8</sup> Under FSMA, the FDA is authorized to take action against a facility based on a reasonable suspicion that the food under the facility's purview presents a serious health hazard. For instance, agency officials who have reason to believe a company's product harbors unsafe levels of contaminants can compel the company to issue a recall, as well as suspend its FDA registration, effectively revoking its license to import or export food to the United States; hire a third party to do so on its behalf; or introduce its products into U.S. intrastate or interstate commerce.

## INDUSTRY RESPONSE

To guarantee the purity and safety of their products and increase their competitiveness in the global marketplace, many enterprises in the coffee chain implement rigorous quality management systems such as Hazard Analysis and Critical Control Point (HACCP) plans. This preventative approach to contamination has long been mandatory in the EU, and under FSMA, U.S. food facilities are now required to ensure their HACCP plans align with an updated model called Hazard Analysis and Risk-Based Preventive Controls (HARPC). These types of systems typically incorporate mold and mycotoxin prevention measures such as good agricultural practices (GAP), rapid drying, and careful maintenance of storage areas and shipping containers. To verify the system's effectiveness, food safety experts generally recommend testing contaminant levels at critical points in the production process. Testing not only enables coffee stakeholders to uncover and address any weaknesses in their hazard control plan, but also serves as the basis for the only completely reliable method of limiting the costly impact of OTA contamination once it exceeds a predetermined threshold. By making it possible for growers, traders, and processors to identify and remove contaminated materials from the production stream, vigilant upstream mycotoxin surveillance helps keep a manageable risk from becoming a major liability.

## OTA TESTING: WHY THE METHOD MATTERS

HACCP plans and many other similar QC programs stipulate the use of a validated test method to confirm that the production process is under control. Methods that meet the demanding performance criteria of third-party standards organizations play an equally essential role in equipping coffee companies for an expanding array of marketplace demands from certifying compliance with domestic and international maximum limits and verifying suppliers'

adherence to accepted safety standards to satisfying the increasingly exacting contractual requirements of high-end buyers. One example of an officially sanctioned method that fits a broad range of user needs is an immunoaffinity (IA) column from Massachusetts-based test developer VICAM, A Waters Business.

VICAM's AOAC-approved [OchraTest™](#) is a streamlined method of preparing coffee samples for instrumental analysis that overcomes the technical challenges of detecting and measuring trace levels of mycotoxins in a complex samples. IA cleanup removes many different chemical components of coffee that can interfere with accurate detection and efficiently extracts its OTA content, minimizing the risk of misclassifying lots based on false-positive or false-negative results. The simplicity of the cleanup procedures also greatly reduces the chances of human error.

The type of instrument used to analyze the purified sample determines the degree of speed, accuracy, and precision as well as the cost and complexity of this advanced rapid method. For real-time decision support in the field, at buying points, and in warehouses, factories, and testing laboratories, the simplest and most economical option is to use OchraTest with a fluorometer. Onsite users and lab technicians can easily use this method to obtain reliable ppb results in less than 15 minutes. The VICAM Series-4EX® fluorometric reader offers the additional advantage of storing as many as 200 test results, easing the task of documenting contamination control procedures.

For applications that demand the highest degree of certainty, VICAM recommends combining IA column cleanup with sophisticated laboratory instruments such as high or ultra performance liquid chromatography (HPLC/UPLC®) or liquid chromatography – mass spectrometry (LC-MS). Performed by highly trained analytical chemists in accredited third-party laboratories, these gold-standard methods guarantee the definitive results required by customs inspectors, food safety officials, and demanding buyers. The certifications issued with these tests also enable coffee industry stakeholders to increase credibility with consumers by demonstrating their commitment to safety, quality, and traceability across the supply chain.

The development of lateral-flow strip tests has made it possible to access many of the benefits of advanced immunoassay technology in a simplified format that makes frequent onsite testing both practical and highly affordable. VICAM's version of this antibody-based quantitative method, Ochra-V® AQUA™ takes as little time as 5 minutes to deliver accurate results and requires no interpretation: a numerical reading is displayed on the digital screen of a handheld optical reader. The test also eliminates the need for organic solvents, reducing the environmental impact as well as the cost of routine QC checks and pre-screening samples in testing labs. These combined advantages make this type of test a valuable option for upstream mycotoxin control in regions where state-of-the-art laboratory instruments are unavailable.

Although laboratory analysis ensures greater sensitivity and precision, this quantitative strip test offers a highly accessible alternative that's solidly grounded in the fundamental principles of accurate mycotoxin detection. Like VICAM's IA columns, Ochra-V AQUA not only harnesses the enhanced capacity of monoclonal antibodies to selectively bind with target analytes but also incorporates the benefits of a statistically valid sampling plan. This approach calls for pooling many small incremental samples taken from different areas of a lot to form an aggregate sample, which is then finely ground in a food mill to obtain a homogeneous sample for testing. These procedures reduce the risk of over- or underestimating the overall OTA concentration in the lot by accounting for the tendency of mycotoxins to cluster in pockets, or "hotspots," in widely scattered locations.

## THE ROI

As new regulations continue to emerge in response to the public's concern about food-borne safety hazards, effective prevention has become an urgent priority for every sector of the food industry. For coffee-sector enterprises, programs that limit the occurrence of OTA across the supply chain are an investment that pays major dividends in increased consumer confidence in their brands and a sharper competitive edge in domestic and foreign markets.

Ultimately their success in bringing the world's most heavily traded commodity to these markets has a profound impact on the health of the today's global economy and the long-term future of the developing countries that sustain the abundance of the coffee supply.

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