

A photograph showing a wooden bowl filled with sesame seeds, resting on a wooden cutting board. A wooden scoop is placed inside the bowl. In the background, there is a white cloth with blue stripes and some scattered sesame seeds on a grey surface.

# Beyond the Big 8: Sesame Allergen Testing

## Introduction

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The prevalence of food allergies in the United States has risen substantially over multiple decades and shows no sign of abatement. Under existing law, FDA has the authority to require manufacturers to ensure clear and appropriate labeling when a new allergen of public health importance is identified. In the case of sesame, the voluntary disclosure guidance published in November 2020 will become mandatory as of January 1, 2023.

This document outlines the existing environment, the challenges and goals of sesame detection, and considerations when evaluating the optimal allergen testing partner.

## Background: Allergens and Food Safety Disclosure Guidelines

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Food allergies affect 32 million Americans equating to an estimated affected population of 1 in 10 adults and 1 in 3 children.<sup>1</sup> Although allergic reactions to more than 170 foods<sup>2</sup> have been reported, the FDA *Food Allergen Labeling and Consumer Protection Act of 2004*, 21 U.S.C. (FALCPA)<sup>3</sup> defined eight major allergens which account for more than 90% of reactions (see Table 1). As of April 23, 2021, FDA's *Food Allergy Safety, Treatment, Education, and Research Act* (FASTER Act) added sesame as the ninth major food allergen.

**Table 1. Prevalence of major FDA-identified food allergies in the US<sup>4,5</sup>**

Big 8 Allergens (2004)	US Prevalence
Shellfish	8.2M
Milk	6.1M
Peanut	6.1M
Tree Nuts	3.9M
Egg	2.6M
Fin Fish	2.6M
Wheat/Gluten	2.4M
Soy	1.9M
<b>NEW Addition: 9th Major Allergen (2023)</b>	
Sesame	0.7M

FALCPA legislation requires on-label disclosure of all major food allergens by common name for clear identification by allergy-affected individuals. Food manufacturers and processors who fail to detect and disclose major allergens face government enforcement action ranging from warning letters to seizure and injunction. Due to the potentially life-threatening nature of these allergic reactions, failure to comply with FALCPA requirements may also result in financially devastating civil lawsuits.

<p><b>Example 1</b>                  Ingredients: Whey protein (milk), lecithin (soy), cherry, sugar, natural flavors (almond), salt.</p>	<p><b>Example 2</b>                  Ingredients: Whey protein, lecithin, cherry, sugar, natural flavors, salt.  <b>Contains: Milk, soy, and almond.</b></p>
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*Examples: On-Label Food Allergen Disclosure<sup>6</sup>*

Currently, it is estimated that more than 80% of US food companies follow a formal food allergen testing process, leaving the balance at risk of undisclosed allergen contamination.

**US Food Allergies:  
Increased Incidence & Impact**

- Childhood food allergies have increased by 50% (1999-2011)<sup>7</sup>
- Prevalence of childhood peanut and tree nut allergies have tripled (1997-2008)<sup>8</sup>
- The cost of caring for children with food allergies is estimated at \$25B annually<sup>9</sup>
- Every 3 minutes, a food allergy reaction results in an Emergency Room visit<sup>10</sup>
- Food-borne anaphylaxis treatments have increased 377% (2007-2016)<sup>11</sup>

Voluntary precautionary statements have been adopted by some companies. However, FDA indicates advisory statements such as “may contain (allergen X)” or “processed in a facility with (allergen X)” are inadequate alternatives to GMP adherence, testing and proper allergen labeling. Virtually all food manufacturers and processors must therefore take definitive action to protect public health and defend against exposure to government action, civil suits, product recall, and brand erosion.

## Sesame: A Commonly Hidden Allergen

Under current law,<sup>xiii</sup> if whole sesame seed is used as an ingredient, it must be declared on the label. However, when sesame is a ground component of a multi-ingredient flavoring (i.e., spice blend), there is no requirement to specifically identify it. Moreover, preparation with sesame oil, and sesame-rich foods including hummus, falafel and a variety of packaged snacks, are largely undeclared today. As such, sesame can be considered a “hidden” allergen putting even greater pressure on companies to reliably detect, clean and correct, or disclose as indicated.

**"What comes into your facility from suppliers has an equally important impact on the quality and integrity of your food processing protocols – and ultimately your legal exposure as well."<sup>12</sup>**

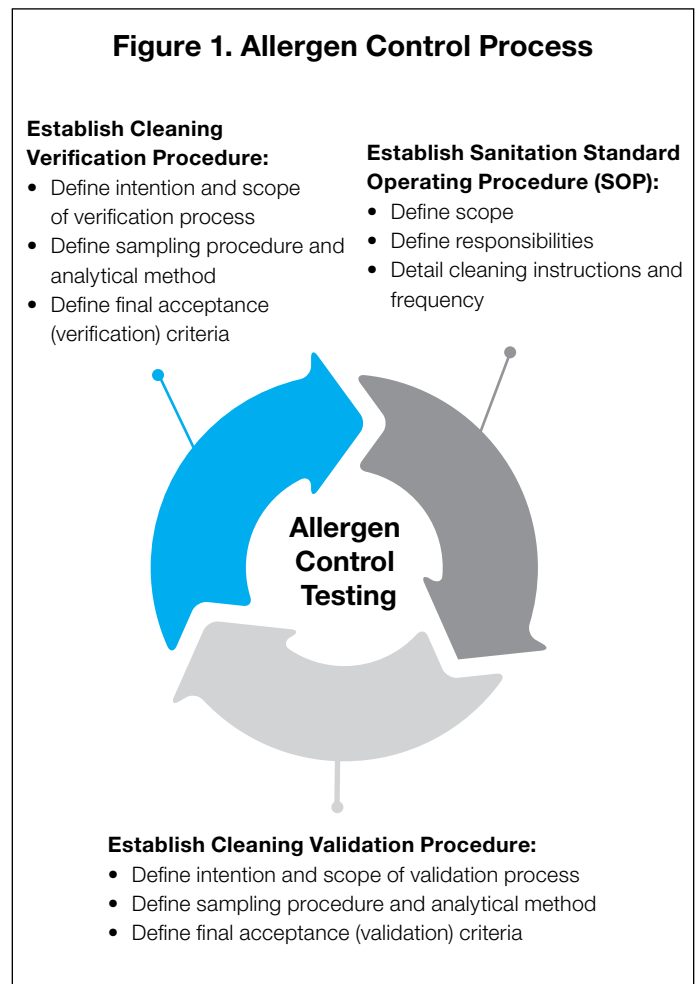
In November 2020, FDA issued a *Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry*.<sup>13</sup> Although the mandatory sesame disclosure requirement does not become effective until January 1, 2023, now is the time to prepare. Facilities must develop an effective allergen testing program as well as optimized sesame detection solutions – this includes food manufacturers, processors and the reference laboratories that serve them. What follows is an overview of the considerations and processes required to do so.

### Allergen Testing Goals

Allergen testing goals are twofold: **Verification** and **Validation**

**Verification** analysis occurs at the site of manufacture/processing according to the facility’s adopted allergen control testing plan. This process includes frequent confirmation (verification) that established cleaning procedures are effectively removing allergen residues. The verification analysis is typically conducted with a

high sensitivity, qualitative immunochromatographic method (e.g., lateral flow device (LFD)).



**Validation** analysis may occur at a manufacturer’s on-site laboratory, or more frequently, at a third-party reference laboratory. This process demonstrates (validates) the efficacy of the on-site, internally verified testing method. Validation is performed prior to adopting a formal cleaning procedure. It is also performed routinely (quarterly, annually, semi-annually) as an integral component of a food safety program. The validation analysis is commonly conducted with a quantitative enzyme-linked immunoassay (ELISA) method.

## Selecting an Optimal Allergen Testing Partner for Your Facility

When selecting the appropriate allergen test partner for verification and validation, several considerations are warranted, including: test sensitivity and specificity, multi-matrix capability, ease of performance, and time-to-results (see Table 2.).

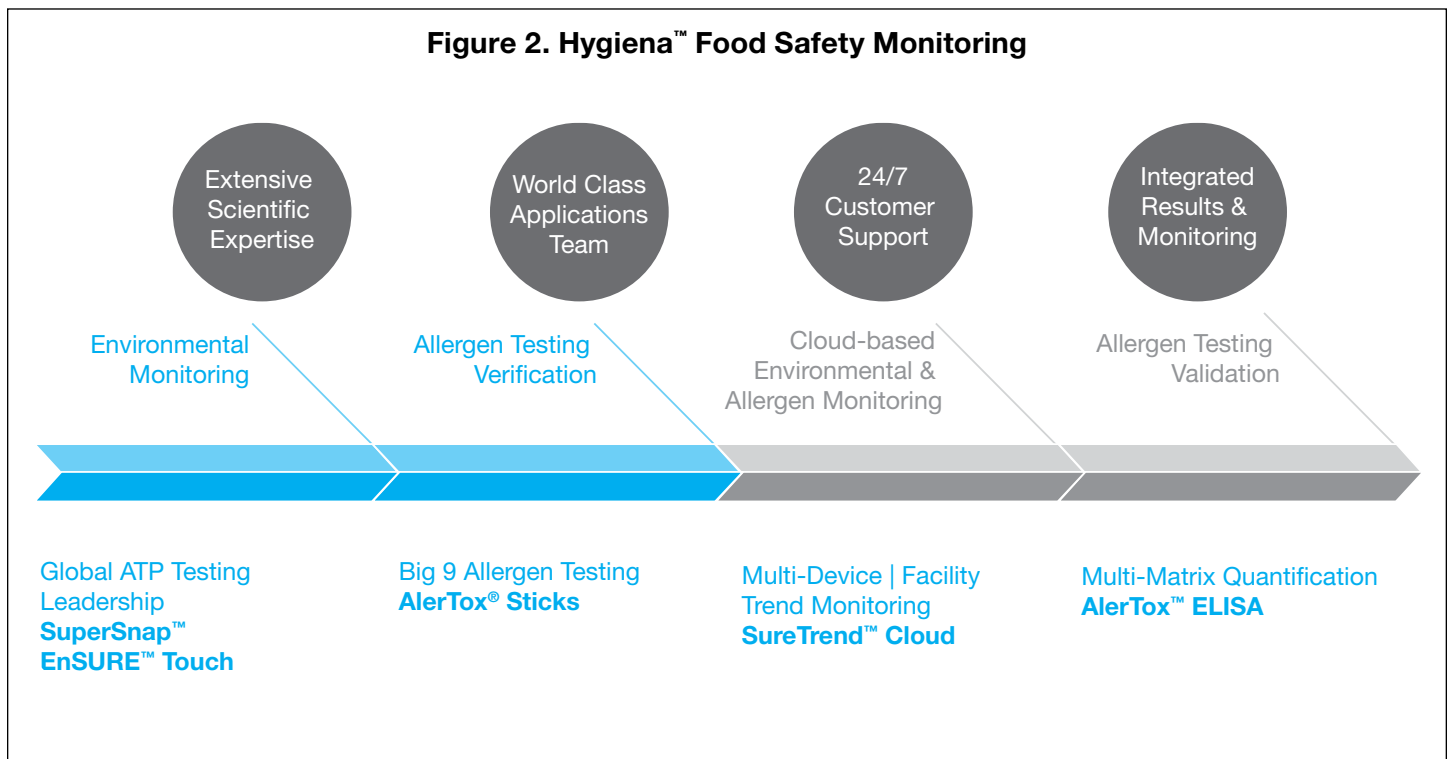
**Table 2. New Allergen Testing Assay Adoption Considerations**

Verification (LFD), On-Site Testing	
Workflow Considerations	Hygiena™ Solution: AlerTox® Sticks, Sesame
High Sensitivity Detection (Limit of Detection (LOD))	<ul style="list-style-type: none"> <li>• 3 ppm (sesame)</li> <li>• Range of Detection: 3-20,000 ppm</li> </ul>
Broad Set of Available Validation Data	<ul style="list-style-type: none"> <li>• &gt; 30 brands/sources validated vs ELISA</li> </ul>
Ease of Use	<ul style="list-style-type: none"> <li>• Lab-in-a-Box approach</li> <li>• No need for additional steps or materials</li> <li>• No refrigeration required</li> <li>• No technical skills required</li> </ul>
Time to Results	<ul style="list-style-type: none"> <li>• 10-minute time-to-results</li> </ul>
Multiple Matrix Testing Capability	<ul style="list-style-type: none"> <li>• Solid, liquid, and surface compatible</li> </ul>
Integrated Cleaning-Testing Protocol	<ul style="list-style-type: none"> <li>• Big 9 allergen testing</li> <li>• EnSURE™ Touch/ATP testing compatible</li> <li>• SureTrend™ Cloud consolidated test tracking</li> </ul>
Unique Benefits	<ul style="list-style-type: none"> <li>• Industry-leading time-to-results equates to faster product release</li> <li>• 24/7 on-demand support maximizes up-time</li> </ul>
Validation (ELISA), Laboratory Testing	
Workflow Considerations	Hygiena™ Solution: AlerTox® ELISA, Sesame
High Sensitivity with Quantification (Limit of Detection (LOD), Limit of Quantification (LOQ))	<ul style="list-style-type: none"> <li>• 0.2 ppm (LOD)</li> <li>• 2.0 ppm (LOQ)</li> </ul>
Available Cross-Matrix Recovery Data	<ul style="list-style-type: none"> <li>• Instant soups: 110%</li> <li>• Crackers: 109%</li> <li>• Dressings: 93%</li> <li>• Sausages: 92%</li> </ul>
Ready Integration into Laboratory Workflow	<ul style="list-style-type: none"> <li>• Room temperature incubation</li> <li>• Total incubation time: 60 mins</li> <li>• Compatible with standard ELISA washers</li> <li>• Compatible with standard ELISA readers (450 nm)</li> </ul>
Comprehensive Allergen Menu	<ul style="list-style-type: none"> <li>• 20 AlerTox® ELISA tests available</li> </ul>
Unique Benefits	<ul style="list-style-type: none"> <li>• Industry-leading scientific expertise</li> <li>• Standard test format allows easy integration with existing processes.</li> </ul>

Beyond test menu and assay specifications, critical considerations when selecting an allergen testing partner also include: breadth of scientific expertise, real-time support, and a commitment to end-to-end, regulatory compliant allergen testing solutions.

## Hygiena™: The One Health Approach to Food Safety and Protection

As a recognized global leader in environmental monitoring, Hygiena™ offers a broad range of high quality, simple-to-use testing solutions. From rapid microbial detection and identification to cleanliness and allergen monitoring tools, Hygiena™ delivers comprehensive food safety technology backed by world-class scientists and applications developers, knowledgeable and localized 24/7 support, proactive innovation, and extensive regulatory expertise to help maintain facility compliance.



## Conclusion

The 2023 inclusion of sesame as a must-declare allergen requires food manufacturers, processors and reference laboratories to prepare. Hygiena™ offers a globally trusted suite of simple and cost-effective cleaning verification, allergen detection, and confirmatory validation technologies for companies of any size. Backed by foundational scientific expertise and on-demand support, Hygiena™ provides the tools for your success.

To learn more, visit [Hygiena.com/sesame](https://www.hygiena.com/sesame).



## References

- <sup>1</sup> *Foodallergy.org*. Accessed Jan 18, 2022.
- <sup>2</sup> *NIAID-Sponsored Expert Panel. Guidelines for the diagnosis and management of food allergy in the United States: Report of the NIAID-sponsored expert panel. J Allergy Clin Immunol. 2010; 126(6):S1- 58.*
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- <sup>4</sup> *Gupta RS, Warren CM, Smith BM, Jiang J, Blumenstock JA, Davis MM, Schleimer RP, Nadeau KC. Prevalence and Severity of Food Allergies Among US Adults. JAMA Network Open 2019; 2(1):e185630.doi:10.1001/jamanetworkopen.2018.5630.*
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- <sup>9</sup> *Gupta R, Holdford D, Bilaver L, Dyer A, Holl JL, Meltzer D. The economic impact of childhood food allergy in the United States. JAMA Pediatr. 2013 Nov; 167(11):1026 -31.*
- <sup>10</sup> *Clark S, Espinola J, Rudders SA, Banerji, A, Camargo CA. Frequency of US emergency department visits for food-related acute allergic reactions. J Allergy Clin Immunol. 2011; 127(3):682-683.*
- <sup>11</sup> *FAIR Health. Food Allergy in the United States: Recent Trends and Costs – An Analysis of Private Claims Data. FARE (Food Allergy Research & Education) Health White Paper, November 2017.*
- <sup>12</sup> *Section 403(i), FD&C Act (21 U.S.C. 343(i)); 21 CFR 101.4*
- <sup>13</sup> *Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry. November 2020. https://www.fda.gov/media/143521/download* Accessed January 21, 2022.