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Food Defense Series – Lessons Learned from Food Defense Audits

Enhancing Compliance with 21 CFR Part 121
(Intentional Adulteration Rule) in the Food
and Beverage Industry

White Paper | October 2025

Introduction

In an era of heightened food safety concerns, intentional adulteration remains a critical threat to the global food supply chain. The U.S. Food and Drug Administration's (FDA) regulation under 21 CFR Part 121, 'Mitigation Strategies to Protect Food Against Intentional Adulteration,' mandates robust food defense measures for facilities handling vulnerable food products. Recent shifts in FDA enforcement, as highlighted in the webinar '[FDA's Approach to Food Defense Inspections](#)' indicate a move from cursory reviews to comprehensive compliance audits. These audits are actively occurring now and there is no way to predict when your audit might occur. This evolution underscores the need for manufacturers to proactively address gaps in their food defense programs.

Drawing from extensive audits conducted by Business Protection Specialists, Inc. ([BPS](#)), this white paper generalizes common compliance shortcomings observed across numerous food and beverage facilities. These insights reveal opportunities for improvement in vulnerability assessments, training, food defense planning, mitigation strategies, records management, and reanalysis.

By addressing these areas, companies can mitigate risks, ensure regulatory compliance, and protect their brands from potential adulteration incidents. Recommendations include conducting thorough gap analyses and adopting standardized tools to streamline processes.

The Evolving Landscape of Food Defense

Food defense focuses on protecting the food supply from intentional acts of contamination, differing from traditional food safety which targets unintentional hazards. Enacted as part of the Food Safety Modernization Act (FSMA), 21 CFR Part 121 requires covered facilities to develop and implement food defense plans that identify vulnerabilities and deploy mitigation strategies.

Historically, FDA inspections emphasized 'quick checks' for basic compliance. However, as detailed in the aforementioned FDA webinar, the agency is now prioritizing in-depth audits, evaluating the full spectrum of a facility's food defense posture. Stellar performance on third-party audits, such as those from the American Institute of Baking (AIB) or British Retail Consortium (BRC), no longer guarantees a clean FDA review. Many companies have been lulled into a false sense of security because previous audits do not look deeply into all areas of compliance required under 21 CFR 121.

BPS audits do the deep dive and therefore consistently identify discrepancies between perceived compliance and regulatory requirements, often stemming from incomplete vulnerability assessments and inadequate documentation on training and records.

This white paper synthesizes lessons from BPS's compliance gap analyses, presenting anonymized, representative findings from typical food manufacturing operations. It aims to guide food and beverage manufacturers in fortifying their programs against emerging inspection rigor, ultimately reducing the risk of intentional adulteration and associated brand impacts.

Common Compliance Opportunities in Food Defense Programs

BPS's regulatory compliance gap analyses against 21 CFR Part 121 reveal recurring themes across audited facilities. The following sections outline key areas of vulnerability, supported by regulatory references and practical examples of shortcomings.

VULNERABILITY ASSESSMENT

§ 121.130

A foundational element of food defense, the vulnerability assessment (VA) must evaluate each point, step, or procedure in a facility's operations to identify significant vulnerabilities and actionable process steps (APS). Common issues include:

- **Insufficient Detail:** Many VAs lack the granularity required, often diverging from Hazard Analysis and Critical Control Points (HACCP) flow diagrams. For instance, processes like partial ingredient storage are frequently overlooked, leading to missed APS, unmitigated risks, and training gaps. HACCP flow diagrams may also miss steps in the process and may need to be modified to better align with an FDA compliant vulnerability assessment.
- **Absence of Representative Contaminant Analysis (RCA):** An RCA is a tool that is presented in the FDA's guidance which may allow certain APS to be ruled out and thus reduces the burden of compliance in areas where there is no true risk to the product. Without an RCA, facilities may retain unnecessary APS, resulting in excess work and record-keeping.

These vulnerability assessment gaps create cascading effects. Negative impacts of inaccurate APS inventory include:

- Inadequate Mitigation Strategies
- Missing Management Controls
- Inadequate Records
- Heightened Exposure to Intentional Adulteration.

RECOMMENDATIONS:

Audits should be conducted by a qualified food defense expert intimately familiar with the IA rule and with an audit methodology that closely aligns with 21 CFR Part 121. Conduct onsite exercises to align VAs with HACCP diagrams and amend both documents accordingly. Consider performing RCAs to refine APS lists and minimize unnecessary compliance burden. These steps will enhance conformance to § 121.130(a)(1-3), minimizes unnecessary burdens and lower the risk of a [FDA Form 483](#) notification.

FOOD DEFENSE PLAN

§ 121.126

The U.S. Food and Drug Administration (FDA) provides the Food Defense Plan Builder (FDPB) as a free, voluntary, user-friendly software tool to assist owners and operators of food facilities in developing a customized food defense plan (FDP) that complies with the requirements of the Intentional Adulteration (IA) rule under 21 CFR Part 121.

FDA inspectors might view the use of the FDPB positively, the current format features some practical shortcomings for thoroughness and the proper management of change. A couple of examples of potential opportunities for improvement would include:

- A record (log) of plan changes. This can be very beneficial to support compliance with reanalysis (§ 121.157).
- Records. The FDPB does not provide a robust means of creating a records inventory and ensuring conformance with [§ 121.305](#).

The FDA emphasizes that the FDPB is optional and not the only acceptable method for creating an FDP—facilities may use alternative formats or tools if all required IA rule components are included (per 21 CFR 121.310).

RECOMMENDATIONS:

Whether or not a facility chooses to use the FDPB or not, a careful review of the overall regulatory requirements to ensure a compliant alternative format or what supplements might be considered for compliance and audit readiness.

MANAGEMENT CONTROLS

§ 121.138

Companies should ensure establishing the appropriate separation of duties in the execution of management controls. BPS has witnessed the person responsible for the implementation of mitigation strategies to be the person responsible for monitoring. This creates some shortcomings such as:

- When the same person implements and monitors a mitigation strategy (e.g., access controls or visual inspections at an actionable process step), they may lack impartiality in assessing their own work. This can lead to subconscious or intentional overlooking of deviations, errors, or inefficiencies.
- FDA guidance emphasizes that food defense must account for inside attackers—individuals with legitimate access who might intentionally undermine strategies. If the implementer is also the monitor, this creates a conflict where self-monitoring could enable or conceal deliberate sabotage, as the person might not report or detect their own non-compliance..
- Monitoring is intended to provide assurances that mitigation strategies are consistently performed and effective (§ 121.140(b)). Without separation, issues like improper implementation (e.g., failure to lock a storage area or conduct a required check) might go unnoticed, heightening the facility's exposure to intentional adulteration aimed at causing wide-scale public health harm.
- In scenarios where monitoring overlaps with implementation (e.g., an operator both performs and checks a process), deviations may not be adequately documented or addressed, leading to gaps in records and corrective actions. This could result in missed opportunities to identify and mitigate risks, potentially escalating to regulatory non-compliance during FDA inspections.

RECOMMENDATIONS:

Companies should maintain the appropriate level of separation of Duties. To mitigate these downsides, establish and maintain flexibility in assigning roles (e.g., using supervisors for monitoring while line personnel implement) and incorporating diverse team input to enhance vigilance against insider threats. Facilities should document procedures clearly in their food defense plan, ensuring monitoring frequency and methods provide reliable assurances of strategy performance.

RECORDS

§ 121.301

The regulation is clear about the structure and format of records used to demonstrate conformance to management controls. Many companies fail to attend to the details and invite findings and unnecessary conversation.

Exception records is a tool offered under FDA guidance, and its judicious use can reduce recordkeeping burden and soft costs associated with compliance.

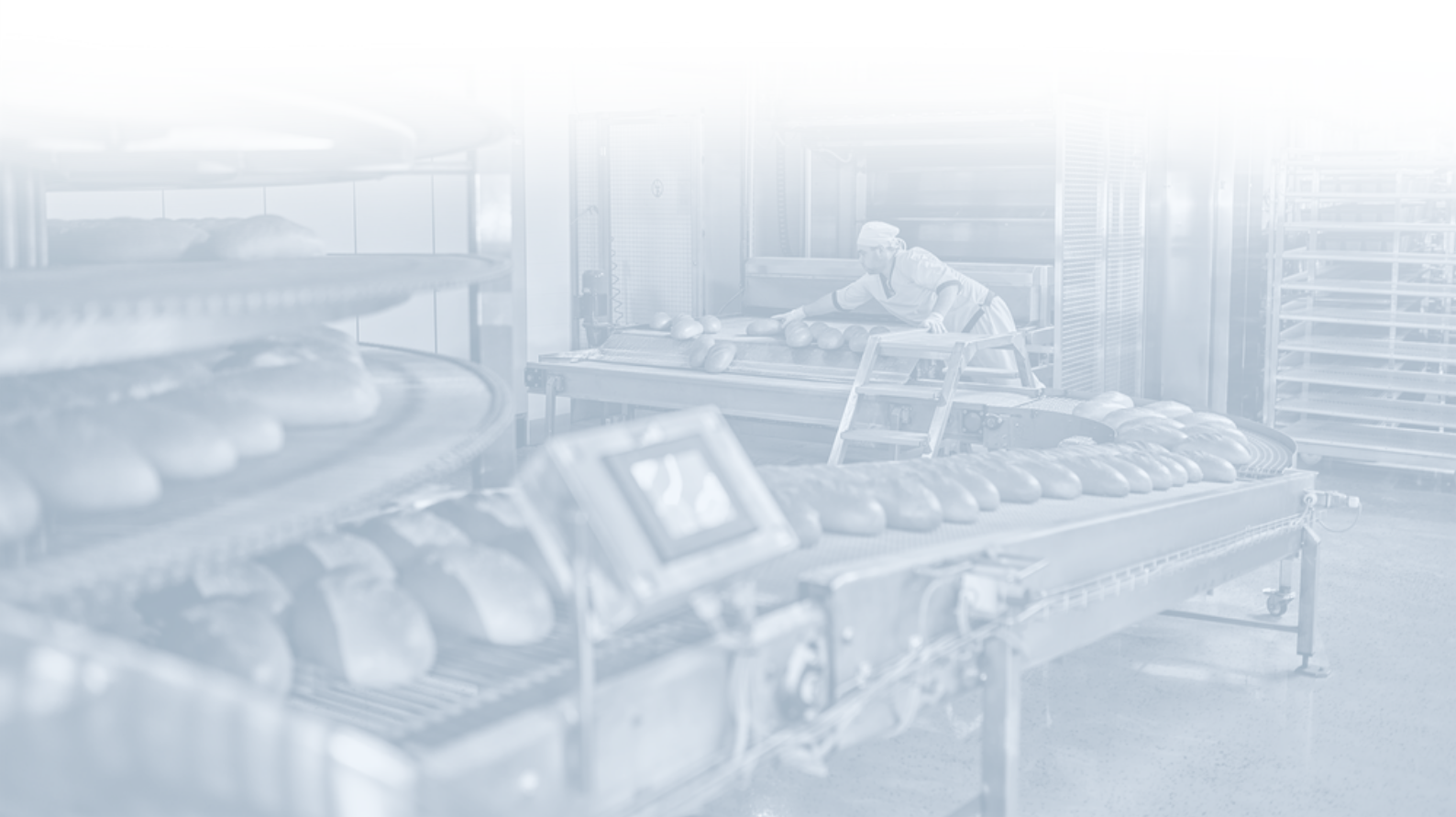


Qualified Individuals (QIs) must be certified through education, training, or experience to perform specific food defense roles. Audits frequently uncover:

- **Incomplete Coverage:** While general food defense awareness training (e.g., via corporate learning management platforms) is often provided to all employees, targeted training for those at APS is inconsistent at best. Supervisors and personnel implementing mitigation strategies may lack role-specific instruction which is a compliance gap.
- **Certification Validity:** Training from sources like AIB's Food Defense Coordinator program (conducted years ago for many facilities) may not align with FDA-recognized syllabi, and AIB recertification every two years is often neglected. This raises audit risks.
- **Tracking Deficiencies:** Decentralized records hinder efficient demonstration of QI qualifications during inspections.

RECOMMENDATIONS:

Develop a centralized training matrix to track qualifications, objectives, and records. This facilitates compliance verification and reduces debate during audits.



Considering the FDA's increased scrutiny on food defense compliance under 21 CFR Part 121, it is essential for food and beverage manufacturers to act proactively to safeguard their operations from the risks associated with intentional adulteration. As highlighted in our audit findings, many companies are overlooking critical gaps in their vulnerability assessments, food defense planning, and training protocols—areas that can lead to regulatory non-compliance and increased exposure to both financial and reputational damage.

Business Protection Specialists, Inc. (BPS) has a proven track record of identifying these gaps and helping organizations mitigate risks before they become costly compliance failures. Our in-depth, independent 21 CFR Part 121 compliance audits are designed to provide a thorough examination of your food defense program, ensuring that you meet all FDA requirements while minimizing unnecessary compliance burdens.

Don't wait for an FDA audit to highlight deficiencies in your food defense plan and program. [Reach out to BPS today](#) to schedule your independent food defense compliance audit and ensure that your facility is fully prepared to handle the evolving regulatory landscape. Protect your brand, ensure compliance, and stay ahead of the curve—contact [BPS](#) to get started.



When done right, **physical security** is not just a cost, it is an investment in your people and organization's future resilience.



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