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Critical Disposable Glove Contamination Risks & Proven Solutions

EXECUTIVE SUMMARY

Food safety professionals face a critical but often overlooked vulnerability in their safety protocols—disposable glove contamination. While companies invest significantly in verifying ingredients, monitoring temperatures, and validating sanitation processes, there exists a concerning gap in the verification of disposable gloves, which are often the last point of contact with food products.

Recent peer-reviewed research revealed multiple evidence based studies of FDA compliant food grade gloves contaminated with foodborne pathogens, containing toxic compounds, and with significant physical defects. However, current FDA food compliance standards only require chemical content and migration testing—testing and verification of cleanliness (microbial contamination) or performance standards (holes and defects) is not required for food compliant gloves.

This creates an uncontrolled variable in food safety systems that could potentially undermine existing HACCP protocols, risking consumer safety, and company liability. This white paper examines the scope of glove contamination risks, their implications for food safety programs and presents evidence-based solutions for closing this critical verification gap.



THE CRITICAL GAP IN FOOD SAFETY PROGRAMS

Regulatory Disconnect

Current FDA (21 CFR 177) compliance for food handling only includes chemical content and migration testing, requiring gloves to be "manufactured from components that are safe and suitable for their intended use". While the FDA Title 21 Part 110 - Good Manufacturing Practice (GMP 21 CFR 110.10) mandates that gloves must be maintained in an "intact, clean, and sanitary condition," there are no specific FDA requirements for testing or verifying these standards.

FDA Food Compliance for Gloves FDA (21 CFR 177)

(FDA Food Compliant gloves **do not comply** with the FDA Good Manufacturing Practice)

FDA Good Manufacturing Practice FDA Title 21 Part 110

Understanding the Verification Gap

Food safety systems are built on verified controls and documentation. Yet when it comes to FDA food compliant disposable gloves:

- Physical integrity testing or standards (holes, tears) are not mandatory
- Bioburden and pathogen identification standards are not required or measured
- Manufacturing facilities have limited quality control and sanitation oversight and inspection

This lack of verification stands in stark contrast to other aspects of food safety programs where multiple hurdles and verification steps are standard practice.

HACCP Implications

This verification gap has serious implications for HACCP-based food safety systems—potentially introducing hazards, while assuming gloves are preventing them:

- 1. Compromised Prerequisites: Gloves are typically considered part of prerequisite programs and assumed intact, clean, and sanitary. But without testing and verification, this assumption may be false.
- 2. Unidentified Hazards: Numerous research has identified harmful toxins, defective gloves, and frank and opportunistic pathogens including Listeria monocytogenes, Clostridoides difficile, and enterotoxigenic strains of Bacillus cereus on new and unused gloves—current standards don't require testing for microbial contamination.
- **3.** Control Point Vulnerability: In many operations, gloves represent the final control point of product contact making their integrity crucial for food safety. If gloves are contaminated, there is no later kill step to remove pathogens.

UNDERSTANDING THE SCALE OF GLOVE CONTAMINATION

Recent research published in the Journal of Food Protection (July 2024) <u>Potential for Glove Risk Amplification</u> via <u>Direct Physical, Chemical, and Microbiological Contamination</u> has identified concerning levels of contamination in unused, food-compliant gloves, including:

- Frank pathogens (Listeria monocytogenes, Bacillus cereus)
- Opportunistic pathogens (Staphylococcus aureus, Pseudomonas aeruginosa)
- Fecal indicator organisms
- Chemical contaminants including phthalates and toxic compounds

The Verification Investment Paradox (*Example here: A \$50M revenue food processor*)

Control Point	Current Verification	Annual Investment
Equipment Surfaces	ATP Testing, Environmental monitoring	\$40,000
Ingredients	Certificates of Analysis, Supplier verification	Significant
Temperature	Continuous monitoring, Calibration	Significant
Disposable Gloves	Chemical content and migration only	Nil

This paradox of no verification process for disposable gloves becomes more striking when considering gloves are defined as a <u>Food Contact Surface (FCS) by the FDA</u>.

Financial Impact

Direct Costs

1. Recall Expenses:

- Product retrieval and destruction
- Investigation and documentation
- Regulatory compliance and legal expenses

Consider current investments in food safety verification:

- 2. Operational Impacts:
 - Production downtime and additional labor costs
 - Replacement product manufacturing
 - Supply chain disruption

Hidden Costs

- Brand damage and loss of consumer trust. A single contamination event can shatter decades of consumer trust. Rebuilding that trust often takes years—if it's possible at all.
 "Chipotle experienced significant financial losses and stock price declines following multistate E. coli outbreaks." Source
- 2. Market share erosion "McDonald's spends \$100 million to lure customers back after E. coli outbreak." CNN
- 3. Regulatory scrutiny and oversight *"FSIS Announces Stronger Measures to Protect the Public from Listeria monocytogenes"* USDA Dec, 2024
- 4. Worker safety claims and litigation "*a single case of dermatitis can cost more than \$10,000 in employer-paid expenses*" OSHA
- 5. Increased insurance premiums



SOLUTION: COMPLETING THE FOOD SAFETY SYSTEM

A comprehensive food safety system requires verification at every critical control point, including disposable gloves, typically the last point of contact with food products. Eagle Protect's range of <u>Delta Zero</u>TM verified gloves offer a science-based solution to completing the food safety system.

Key Components of Eagle's Lot-based Delta ZeroTM Verified Gloves

1. Raw Material Consistency

- Verification of consistent quality, performance, and durability
- Verification of barrier effectiveness

2. Chemical Contamination Screening

- Verification of absence of harmful compounds
- Advanced migration testing

3. Microbiological Testing

- Bioburden levels assessed
- Pathogen screening

Implementation Strategy

Glove safety within a HACCP plan can be immediately strengthened by:

1. Risk Assessment

- Evaluate current glove selection and usage protocols
- Identify critical control points
- Review any historical incidents

2. Program Development

- Establish glove selection, usage, and food safe verification practices and protocols
- Define acceptance criteria
- Create documentation systems to meet facility requirements

3. Integration with Existing Systems

- Align with HACCP principles
- Incorporate into prerequisite programs
- Update supplier verification programs

Return on Investment

Consider the investment comparison:

• Current ATP testing of potential food contact surfaces: \$40,000 annually

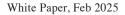
<u>DELTA ZER</u>

<u>Quality Verification Program</u>

• Verified glove program: \$0.00-0.02 per glove premium

The minimal cost difference provides:

- Documented verification of cleanliness (microbial contamination), toxic profile and performance standards (holes and defects) through lot-based testing
- Unique full supply chain traceability: Manufacturer to end user enhancing existing food safety systems and HACCP plans
- Protection against recall risks and brand damage
- Worker safety protection



DISCUSSION

The question is no longer whether to implement glove verification, but rather: How can we claim to have a complete food safety system without verification at the last point of contact?

With verification technology now available, companies have the opportunity to:

- 1. Complete their food safety systems with comprehensive glove verification
- 2. Protect their brands and consumers from contamination risks
- 3. Lead the industry in food safety excellence

Implementing verified glove testing protocols and standards for microbial contamination and glove food safety performance is the solution to closing the critical gap in food safety systems. Eagle Protect's proprietary glove testing and verification program (Delta ZeroTM) has been established over a five year period and proactively safeguards customers' food and business practices.

Leadership in establishing proactive glove verification standards will protect both public health and company interests, while strengthening overall food safety systems.

SUGGESTED NEXT STEPS

1. Literature Review:

- Pull and analyze the cited Journal of Food Protection (July 2024) article
- Review <u>FSIS announcement</u>: Effective January 2025, FSIS will add broader Listeria species testing to all samples of RTE product, environmental samples, and food contact surface samples
- Examine any related regulatory guidance changes from late 2024

2. Urgent Supplier Engagement:

- Contact glove suppliers to ascertain proof of current testing and verification protocols
- Request their response to the Journal of Food Protection (July 2024) findings

3. Internal Protocol Review:

- Assess glove selection, usage, and food safety verification practices and protocols
- Establish a new specific Standard Operating Procedure (SOP) for glove sourcing including supplier testing and verification protocols in addition to FDA Compliance and in accordance with the GMP

APPENDIX: INSIGHTS FROM THE JUST-RELEASED JANUARY 2025 BOAR'S HEAD REPORT

In January 2025, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) released its detailed report on the Boar's Head Listeria monocytogenes (Lm) outbreak. To date, this outbreak, which occurred between May and November 2024, resulted in 61 illnesses, 60 hospitalizations and 10 deaths across 19 states. The investigation traced the source to systemic sanitation failures and lapses in contamination control at a ready-to-eat (RTE) meat production facility.

The Boar's Head report underscores the need for enhanced testing, detection strategies and proactive measures to address foodborne pathogen risks. Among the key findings:

- Systemic Oversights: Gaps in sanitation protocols and inadequate monitoring allowed Lm to persist and crosscontaminate food contact surfaces.
- **High-Stakes Impact:** Over 7 million pounds of meat were recalled, with significant financial losses and long-term brand damage.
- Long-Term Impact to Society: Illness and death

These findings reinforce the importance of addressing critical gaps in food safety systems, including an often overlooked risk: the contamination of disposable gloves and personal protective equipment (PPE).

The Role of Delta Zero[™] Testing in Closing Critical Gaps

Eagle Protect's <u>Delta Zero</u>TM testing program directly addresses the vulnerabilities highlighted in the Boar's Head report by:

- 1. **Proactively Detecting Pathogens:** Delta ZeroTM tests disposable gloves for dangerous pathogens, before they enter the food chain, preventing contamination at the source.
- 2. Enhancing HACCP Compliance: By verifying gloves as a critical control point (CCP), the program ensures that this last point of contact with food products is accounted for within a comprehensive food safety system.
- 3. Minimizing Cross-Contamination Risks: Through independent glove testing, Delta Zero[™] reduces the likelihood of pathogen transfer from gloves to food, which was identified as a key risk in the Boar's Head outbreak.
- 4. Safeguarding Brand Integrity: Implementing rigorous testing prevents costly recalls, protects consumer trust, and aligns with FSIS's call for strengthened oversight and verification.

Key Takeaway

The Boar's Head outbreak serves as a cautionary tale of the catastrophic consequences of systemic food safety failures. Eagle Protect's Delta ZeroTM program offers a science-based, proactive solution to prevent such incidents by addressing the often-ignored risk of contaminated disposable gloves. In doing so, it not only aligns with evolving FSIS recommendations and GMP mandates, but also sets a new standard for food safety excellence.



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Steve Ardagh, is founder and CEO of specialist glove supplier Eagle Protect, the only U.S. glove supply company to conduct proprietary third-party glove testing analysis of their range of gloves. Ardagh has over 20 years experience in the field and is an advocate for increased glove food safety awareness and regulations.