

CORRECTIVE AND PREVENTIVE ACTION (CAPA) REPORT

Report ID: CAPA-2026-045 **Date Issued:** March 31, 2026 **Manufacturer (Co-man):** Apex Co-Manufacturing Solutions **Brand/Client:** [Insert Brand Name] **Product Name:** Chocolate Peanut Butter Protein Bar (50g) **Lot / Batch Number:** #10459 **Report Prepared By:** Jane Doe, Quality Assurance Manager

1. PROBLEM DESCRIPTION

Issue Reported: A customer reported finding a small, soft blue foreign object embedded in the protein bar. **Date of Incident:** March 25, 2026 **Severity:** High (Potential physical hazard / Food Safety risk)

2. INVESTIGATION & ROOT CAUSE ANALYSIS

Investigation Summary: Upon receiving the complaint and the photographic evidence from Foodwit, our Quality Assurance team initiated an immediate review of the production line utilized for Lot #10459 on March 15, 2026. Metal detector logs and X-ray logs showed no anomalies, indicating the material was non-metallic and low-density.

Root Cause (5 Whys):

1. *Why was there blue plastic in the product?* A piece of a blue silicone scraper broke off during the mixing phase.
2. *Why did it break off?* The scraper was worn out and compromised at the edge.
3. *Why was a worn scraper used?* The operator did not notice the wear and tear before starting the shift.
4. *Why wasn't the wear noticed?* There is no mandatory physical inspection of hand tools logged before the mixing process begins.
5. *Why is there no mandatory inspection?* Standard Operating Procedures (SOPs) currently only require end-of-week tool audits, not daily or per-shift inspections.

Identified Root Cause: Lack of daily, pre-operational inspection procedures for degradable production tools.

3. CORRECTIVE ACTIONS (Immediate)

- **Hold Placed:** All remaining inventory of Lot #10459 currently in the warehouse has been placed on QA hold pending further evaluation.

- **Tool Replacement:** All blue silicone scrapers on Line 3 were immediately removed and replaced with new ones.
- **Line Inspection:** A full visual inspection and deep clean of the mixing and extrusion equipment on Line 3 was conducted to ensure no other fragments remained.

4. PREVENTIVE ACTIONS (Long-Term)

- **SOP Update:** The Pre-Operational Checklist SOP has been updated to include a mandatory visual inspection and sign-off for all silicone and plastic hand tools at the start and end of every shift.
- **Material Upgrade:** Procurement has initiated a transition from standard blue silicone scrapers to metal-detectable and X-ray-visible silicone scrapers. The transition will be fully completed by April 15, 2026.
- **Employee Training:** All mixing station operators will undergo mandatory retraining on the new tool inspection SOP by April 5, 2026.

5. VERIFICATION & CLOSURE

Verification Plan: The QA Manager will audit the new daily Pre-Operational Checklists twice a week for the next 90 days to ensure 100% compliance with the new tool inspection protocol.

Target Completion Date for all Actions: April 15, 2026

Signatures: QA Manager: _____ Plant Manager: _____