

BatchBuddy

FSMA Preventive Controls

Readiness Checklist

For Food Manufacturers & Co-Manufacturers

Regulation FSMA 21 CFR Part 117 — Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls

GFSI Alignment SQF Edition 9 / BRCGS Issue 9 — alignment notes included throughout

Audience Food manufacturers, CPG brands, and co-manufacturers subject to FSMA Subpart C

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HOW TO USE THIS CHECKLIST

FSMA Preventive Controls Self-Assessment

This checklist covers the core requirements of FSMA 21 CFR Part 117 (Subparts A–G) for food manufacturers subject to preventive controls obligations. It includes alignment notes for SQF Edition 9 and BRCGS Issue 9 where the requirements overlap. Rate each item: ✓ **Compliant**, ■ **Gap**, or X **Not in place**.

SUBPART B — CURRENT GOOD MANUFACTURING PRACTICE (§117.10–§117.93)

GFSI Alignment: SQF 2.3 / BRCGS 4.1

| § Ref | Requirement | Priority | GFSI Ref | Status |
|---------|---|----------|-----------|----------------------------------|
| §117.10 | Written procedures for qualifications and training of all food handlers and supervisors | High | SQF 2.3.1 | ■ Compliant ■ Gap ■ Not in place |
| §117.20 | Physical plant and grounds maintained to prevent contamination — documented inspection schedule | Medium | BRCGS 4.6 | ■ Compliant ■ Gap ■ Not in place |
| §117.35 | Sanitary operations: cleaning schedules, sanitizing procedures, and pest control documented | High | SQF 11.3 | ■ Compliant ■ Gap ■ Not in place |
| §117.37 | Sanitary facilities: handwashing, toilet, and refuse disposal documented and adequate | Medium | BRCGS 4.8 | ■ Compliant ■ Gap ■ Not in place |

| § Ref | Requirement | Priority | GFSI Ref | Status |
|---------|--|----------|-----------|----------------------------------|
| §117.40 | Equipment and utensils: design, construction, maintenance, and cleaning records in place | High | SQF 6.1 | ■ Compliant ■ Gap ■ Not in place |
| §117.80 | Personnel hygiene controls documented — illness exclusion, hygienic practices, training | High | BRCGS 7.1 | ■ Compliant ■ Gap ■ Not in place |
| §117.93 | Holding and distribution of human food by-products for animal food documented | Low | — | ■ Compliant ■ Gap ■ Not in place |

SUBPART C — HAZARD ANALYSIS & RISK-BASED PREVENTIVE CONTROLS (§117.126–§117.190)

GFSI Alignment: SQF 2.4 / BRCGS 2.1

| § Ref | Requirement | Priority | GFSI Ref | Status |
|----------|---|----------|------------|----------------------------------|
| §117.126 | Written food safety plan exists and is signed/dated by a Preventive Controls Qualified Individual (PCQI) | High | SQF 2.4.1 | ■ Compliant ■ Gap ■ Not in place |
| §117.130 | Hazard analysis completed for each type of food manufactured — biological, chemical, physical, radiological | High | BRCGS 2.2 | ■ Compliant ■ Gap ■ Not in place |
| §117.135 | Process preventive controls identified and implemented for hazards requiring a preventive control | High | SQF 2.5 | ■ Compliant ■ Gap ■ Not in place |
| §117.136 | Allergen preventive controls documented — labeling controls, prevention of cross-contact | High | BRCGS 5.3 | ■ Compliant ■ Gap ■ Not in place |
| §117.137 | Sanitation preventive controls documented for environmental pathogens and food-contact surfaces | High | SQF 11.3 | ■ Compliant ■ Gap ■ Not in place |
| §117.139 | Supply chain preventive controls — supplier verification program for ingredients with hazards | High | SQF 2.6 | ■ Compliant ■ Gap ■ Not in place |
| §117.140 | Recall plan documented — procedures for lot identification, recovery, and notification | High | BRCGS 3.11 | ■ Compliant ■ Gap ■ Not in place |
| §117.145 | Monitoring procedures for each preventive control — frequency, method, and responsible person documented | High | SQF 2.5.3 | ■ Compliant ■ Gap ■ Not in place |
| §117.150 | Corrective actions documented for each preventive control — what to do when monitoring limits are exceeded | High | BRCGS 3.7 | ■ Compliant ■ Gap ■ Not in place |
| §117.155 | Verification activities documented — calibration, testing, records review, reanalysis schedule | High | SQF 2.5.5 | ■ Compliant ■ Gap ■ Not in place |
| §117.160 | Validation: evidence that preventive controls are effective at controlling identified hazards | High | SQF 2.5.2 | ■ Compliant ■ Gap ■ Not in place |
| §117.165 | Product testing, environmental monitoring, and records review conducted per written procedures | High | BRCGS 4.11 | ■ Compliant ■ Gap ■ Not in place |
| §117.170 | Reanalysis of food safety plan triggered by changes in production, facility, or emerging hazards | Medium | SQF 2.4.6 | ■ Compliant ■ Gap ■ Not in place |
| §117.180 | PCQI qualification documented — training certificate or equivalent experience on file | High | — | ■ Compliant ■ Gap ■ Not in place |

| § Ref | Requirement | Priority | GFSI Ref | Status |
|----------|---|----------|----------|----------------------------------|
| §117.190 | Written food safety plan available for FDA review during inspection | High | — | ■ Compliant ■ Gap ■ Not in place |

FSMA 204 — FOOD TRACEABILITY (21 CFR Part 1, Subpart S)

GFSI Alignment: BRCGS 3.9 / SQF 2.6.2

| § Ref | Requirement | Priority | GFSI Ref | Status |
|-------|--|----------|-----------|----------------------------------|
| 204.1 | Food covered under the Food Traceability List (FTL) has been identified — RTERF, fresh produce, shell eggs | High | — | ■ Compliant ■ Gap ■ Not in place |
| 204.2 | Critical Tracking Events (CTEs) are documented: receiving, transformation, creation, shipping | High | SQF 2.6.2 | ■ Compliant ■ Gap ■ Not in place |
| 204.3 | Key Data Elements (KDEs) captured for each CTE — lot code, location, date, quantity, reference record | High | BRCGS 3.9 | ■ Compliant ■ Gap ■ Not in place |
| 204.4 | Full lot trace executable within 24 hours — forward to customers, backward to suppliers | High | — | ■ Compliant ■ Gap ■ Not in place |
| 204.5 | Traceability records retained for 2 years and available to FDA within 24 hours of request | High | — | ■ Compliant ■ Gap ■ Not in place |

SUPPLY CHAIN PROGRAM (§117.139 / FSMA Supplier Verification)

GFSI Alignment: SQF 2.6 / BRCGS 3.5

| § Ref | Requirement | Priority | GFSI Ref | Status |
|-------|--|----------|-------------|----------------------------------|
| SCP-1 | Approved supplier list exists; all raw material suppliers are on it with current approval status | High | SQF 2.6.1 | ■ Compliant ■ Gap ■ Not in place |
| SCP-2 | Written supplier verification procedures define verification activities by supplier risk level | High | BRCGS 3.5.1 | ■ Compliant ■ Gap ■ Not in place |
| SCP-3 | Supplier COAs are received, reviewed, and stored for all lot deliveries of hazard-controlled ingredients | High | SQF 2.6.2 | ■ Compliant ■ Gap ■ Not in place |
| SCP-4 | On-site supplier audits conducted or documented for high-risk suppliers at defined frequency | Medium | BRCGS 3.5.3 | ■ Compliant ■ Gap ■ Not in place |
| SCP-5 | Food fraud vulnerability assessment (FFVA) completed and documented for all ingredients | High | BRCGS 5.4 | ■ Compliant ■ Gap ■ Not in place |
| SCP-6 | FFVA mitigation plan documented for every significant vulnerability identified | High | SQF 2.6.4 | ■ Compliant ■ Gap ■ Not in place |

RECORDS & CORRECTIVE ACTIONS (§117.190–§117.210)

GFSI Alignment: SQF 2.5.4 / BRCGS 3.7

| § Ref | Requirement | Priority | GFSI Ref | Status |
|----------|---|----------|----------|----------------------------------|
| §117.190 | All food safety plan records retained for at least 2 years from creation date | High | — | ■ Compliant ■ Gap ■ Not in place |

| § Ref | Requirement | Priority | GFSI Ref | Status |
|----------|--|----------|-------------|----------------------------------|
| §117.195 | Records created contemporaneously — at the time monitoring, corrective actions, and verification occur | High | BRCGS 3.7.2 | ■ Compliant ■ Gap ■ Not in place |
| §117.200 | Records are legible, permanent, accurate, and indelible — or electronic records meeting Part 11 controls | High | — | ■ Compliant ■ Gap ■ Not in place |
| §117.210 | Corrective action records exist for every preventive control deviation — what happened, what was done, outcome | High | SQF 2.5.4 | ■ Compliant ■ Gap ■ Not in place |

90-DAY AUDIT READINESS PLAN

Priority action sequence for food manufacturers

Days 1–30: Food Safety Plan Foundation · HIGH PRIORITY

- Confirm written food safety plan exists, is signed by a PCQI, and covers all product types manufactured
- Verify hazard analysis is complete for every product line — biological, chemical, allergen, physical hazards identified
- Audit preventive controls documentation — process controls, allergen controls, sanitation controls, supply chain program
- Confirm FSMA 204 Key Data Elements are being captured for all Food Traceability List items
- Enroll BatchBuddy and begin digital batch record capture with FSMA 204 lot traceability active

Days 31–60: Records & Supplier Verification · MEDIUM PRIORITY

- Import historical batch records and supplier COAs into BatchBuddy; link to lot records
- Build out CAPA records for any open deviations or corrective actions from prior audits
- Complete or update Food Fraud Vulnerability Assessment (FFVA) with mitigation plan
- Verify training records for all PCQI-designated personnel and production staff
- Run first bidirectional FSMA 204 lot trace; document results and close any gaps

Days 61–90: Audit Simulation & Verification · COMPLETE & VERIFY

- Conduct mock SQF/BRC audit using the GFSI scheme's published audit checklist
- Run full recall simulation with signed BatchBuddy report — verify forward and backward trace coverage
- Verify environmental monitoring program is current and records are complete
- Confirm all corrective action records trace from trigger to closure with effectiveness verification
- Generate locked BatchBuddy compliance summary — ready for FDA investigator or GFSI auditor review