

Sustainable Food Safety 201



PEAK SHIFT

CHAPTER 10

Food Safety Management Systems

Connect the rule to the work

2026 FDA model Code | 1-201.10 Food Safety Management System; 2-103.11; 8-201.15

BASIS: FDA CODE + TEACHING INTRODUCTION



Active Control and Food Safety Culture

Before service

Assign the control, train the employee, and provide working tools.

During service

Observe or measure the process and respond to a failed check.

After the check

Verify the response and change the system when the cause remains.

Culture in practice

Make accurate reporting expected and supported, even when the result delays service.

Active control is preventive work, not preparation for the next inspection.

The Five Major Risk Factors

Improper holding

Food spends time outside the required temperature control.

Inadequate cooking

The required pathogen-control treatment is not achieved.

Contaminated equipment

Food-contact surfaces transfer contamination to food.

Unsafe sources

Food enters without an approved, dependable source.

Poor personal hygiene

Employee practices transfer contamination to food.

Find the failed control, not merely the untidy appearance.

Five Public Health Interventions

Knowledge

The person in charge understands the operation's hazards and controls.

Employee health

Reporting, exclusion, and restriction interrupt illness transmission.

Hands

Handwashing and ready-to-eat food protection interrupt contamination.

Time and temperature

Control pathogen survival and growth at the relevant steps.

Consumer advisory

Disclose specified raw or undercooked animal foods and provide the increased-risk reminder.

The advisory communicates risk; it does not remove the hazard.

The Person in Charge on Every Shift

Presence	Default: a person in charge is present during all operating hours; stated exceptions apply.
Oversight	Observe handwashing, receiving, cooking, cooling, holding, thawing, and sanitizing.
People	Provide duty-specific food safety and allergy training; verify health-reporting communication.
Qualifications	Certification and demonstrated knowledge do not replace daily oversight.

Employees can perform checks; the PIC must ensure the controls are carried out.

2-101.11; 2-102.11-.12; 2-103.11

BASIS: FDA MODEL CODE + GUIDANCE

The Written Management System

Procedures

Explain the operation's specific controls.

Training plans

Prepare employees to perform their assigned work.

Monitoring records

Preserve the results of operational checks.

Adoption matters

Within 4 years of authority adoption; minimal-risk exclusion is the authority's determination.

The four-year clock starts with authority adoption, not FDA publication or a restaurant's opening.

Prerequisite Programs Support HACCP

Basic conditions

Approved suppliers, safe water, employee health, hygiene, and pest prevention.

Daily methods

Cleaning and sanitizing, maintenance, allergen controls, and employee training.

Process controls

HACCP addresses significant hazards within the specific food process.

A HACCP plan cannot compensate for a broken sanitation foundation.

Annex 4, sections 2(B), 3(B); 2-103.11

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Map the Actual Food Flow

Same-day service

Receive > store > prepare > cook > hold > serve.

Next-day service

Add cooling, cold storage, and reheating where they actually occur.

Confirm the map

Walk the process; include transfers, delays, equipment, and intended consumers.

A missing process step can hide a hazard from the plan.

8-201.14(B)-(D); Annex 4, sections 3(A), 4

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HACCP Principles 1 Through 3

1 | Hazard analysis

Identify significant biological, chemical, and physical hazards and control measures.

2 | Critical control points

Choose the steps where control is essential for food safety.

3 | Critical limits

Set scientifically supported, measurable boundaries at each CCP.

Hazard first, essential control step second, measurable boundary third.

HACCP Principles 4 Through 7

4 | Monitoring

Specify what is checked, how, when, and by whom.

5 | Corrective actions

Predetermine the response when a critical limit is not met.

6 | Verification

Check the plan's validity and whether the system follows it.

7 | Records

Document the plan, checks, deviations, responses, and verification.

A check needs a planned response and evidence of what happened.

Analyze Hazards, Not Just Defects

Biological

Pathogens can survive cooking or grow during poorly controlled cooling.

Chemical

Allergen cross-contact or chemical contamination can make food unsafe.

Physical

A broken component can introduce hard or sharp fragments.

Significance

Evaluate likelihood without control and severity; separate safety from quality.

A treatment must address the actual hazard, not just improve the food's appearance.

A CCP Is an Essential Control Step

Process step

Cooking can be a CCP for pathogen survival in raw poultry.

Safety boundary

The required internal endpoint is the critical limit, not the CCP's name.

Not every task

Quality checks and general housekeeping are not automatically CCPs.

Choose CCPs from the hazard analysis for this operation.

1-201.10; Annex 4, section 3(B); 3-401.11(A)(3)

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Critical Limits Need Complete Conditions

Initial poultry cooking

Conventional cooking: all parts reach 165 F (74 C), instantaneous.

Ordinary cooked-TCS cooling

135 F to 70 F within 2 hours; 135 F to 41 F or below within 6 hours total.

House target

An earlier warning point can help staff act; it does not replace the critical limit.

Keep food, process, purpose, time, and temperature attached to the limit.

3-401.11(A)(3); 3-501.14(A); Annex 4, section 3(C)

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Monitoring Must Produce Usable Evidence

Specify the check

Name the food, parameter, method, frequency, and responsible employee.

Check the food

Use suitable, accurate instruments and the procedure's required measurement locations.

Record the result

Identify the batch and actual result when the observation is made.

Monitoring asks whether this process is meeting its limits now.

8-201.14(E)(4); Annex 4, section 3(D); 4-203.11; 4-502.11(B)

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Correct the Food and the Cause

Control the batch

Keep affected food from service and follow the applicable corrective procedure.

Fit the facts

An unfinished cook differs from unknown storage abuse or chemical contamination.

Close the loop

Recheck, document disposition, and address why the deviation occurred.

Further cooking is not a universal rescue for unsafe food.

Annex 4, section 3(E); 3-401.11(A)(3); 3-701.11

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Verification Checks the System

Review

Check completed monitoring and corrective-action records against the plan.

Observe

Confirm employees use the specified methods and instruments are reliable.

Reassess

Investigate repeated failures and changes in equipment, recipe, or production.

Verification is more than collecting another routine batch reading.

Validation Establishes That the Control Can Work

Scientific question

Will this process, correctly implemented, control the identified hazard?

Evidence

Evaluate applicable scientific and technical support for the actual product and conditions.

Relationship

Validation is a component of verification, not an eighth HACCP principle.

A complete log shows what was done; validation addresses whether the chosen control is adequate.

Records Must Reconstruct the Decision

Plan documents

Keep the process, limits, methods, training, and supporting evidence.

Operating records

Link the batch to readings, deviations, corrective actions, and final disposition.

Review records

Preserve verification findings and follow-up; use applicable retention requirements.

A blank or invented entry is not evidence of control.

8-201.14(E)(7),(F); Supplement 8-103.12(C); Annex 4, section 3(G)

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Worked Flow: Cooling Cooked Soup

Batch record

135 F at 1:00; 68 F at 2:40; 40 F at 6:20. Both cooling stages are met.

Early warning

An early check trending too warm calls for prompt method adjustment and rechecks.

Failed stage

A batch still above 70 F at 3:00 has missed the first-stage limit.

A later cold reading cannot prove an earlier cooling stage was met.

3-501.14(A); 3-501.15; 3-701.11; Annex 4, section 3(D)-(G)

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What a Required HACCP Plan Contains

Describe	Identify the operation, food categories, ingredients, equipment, and actual process flow.
Control	For each CCP: hazard, limit, monitoring method and frequency, and responsible person.
Respond and verify	Specify deviations, corrective actions, verification methods, frequency, and records.
Support	Include training, blank forms, scientific support as required, and requested information.

A generic checklist is not a complete process-specific HACCP plan.

8-201.14(A)-(G)

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Variance and HACCP Are Different

Variance

The regulatory authority grants a modification or waiver of a Code requirement.

HACCP plan

The operation explains how significant process hazards will be controlled.

Writing a plan does not grant permission to depart from a requirement.

Match the Plan to Its Approval Route

Variance activity	Obtain the variance and submit the required HACCP plan for approval before starting.
Qualified ROP route	Some reduced-oxygen packaging needs no variance but still requires advance HACCP submission.
Narrow exception	A qualifying 48-hour ROP process can be exempt from the HACCP-plan requirement.
Local confirmation	Submission, approval, and exemption are different states; confirm the applicable route.

No variance does not mean no controls or no paperwork.

Respond to an Imminent Health Hazard

Default response

Immediately discontinue operations and notify the regulatory authority when the hazard may exist.

Unaffected area

An area truly unaffected by the hazard need not discontinue operations.

Utility exception

For extended power/water loss: authority agreement, approved plan, immediate controls, and notice.

Examples

Sewage backup, fire, flood, toxic-material misuse, or an apparent foodborne-illness outbreak.

A written emergency plan alone does not authorize continued operation.

1-201.10; 8-404.11(A)-(C)

BASIS: FDA MODEL CODE + GUIDANCE

Crisis Preparation, Response, and Recovery

Prepare

Document contacts, decision roles, safe alternatives, and staff practice before an emergency.

Respond

Control the hazard, make required notifications, record facts, and cooperate with the authority.

Guest report

Record reported facts; a complaint alone does not establish the cause.

Recovery

Correct the hazard, resolve affected food, and obtain authority approval before resuming stopped operations.

Equipment repair is not the same as permission to reopen.

2-201.11(A)(2),(B); 8-404.11-.12

BASIS: FDA MODEL CODE + GUIDANCE

Chapter Recap | Management Decisions

Prevent

Connect risk factors to procedures, training, monitoring, and PIC oversight.

Control

Analyze hazards; choose CCPs and limits; monitor, correct, verify, and keep records.

Distinguish

Monitoring checks the process; validation supports effectiveness; verification checks the system.

Escalate

Use the correct variance or plan route; stop, notify, and obtain reopening approval when required.

Name the hazard, the control, the evidence, and the person responsible.

Annex 4; 2-103.11; 8-201.13-.15; 8-404.11-.12; Supplement

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